

### REMARKS

Claims 1-37 and 58-67 are active. New Claims 58-67 find support in original Claims 38-57. Methods of administering the coated cottonseed product to livestock are described throughout the specification, which describes the coated cottonseed product as a "feed". Other minor editorial changes have been made to the claim set. Accordingly, the Applicants do not believe that any new matter has been added.

The Applicants thank Examiner Levy for the courteous and helpful interview of December 18, 2003. It was suggested that the prior art rejections may be withdrawn if the claims were limited to "intact cottonseed" to distinguish them from products such as cottonseed meal and if the Applicants further elaborated on how the prior art does not disclose coating intact cottonseeds with the combination of a metal and a phosphate. It was also suggested that the claim set be limited to particular classes of ingredients for clarity and to avoid the prior art. Accordingly, certain dependent claims are directed to specific compounds, e.g. Claims 3 and 16 are limited to glutamic acid fermentation solubles, other claims are limited to specific phosphorous or metal compounds. To address the enablement rejection of the specific method of treatment claims, it was suggested that claims directed to administering or feeding the coated cottonseed products to livestock be presented. The Applicants have now amended the claim set in accordance with these suggestions. Favorable consideration is requested.

### Restriction

The Applicants thank Examiner Levy for indicating that the Restriction Requirement has been withdrawn.

Rejection--35 U.S.C. 112, second paragraph

Claims 1-57 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for the recitation of certain terms. The Applicants respectfully submit that the following terms are not indefinite, but conventional and well-known in the art as shown by the attached Official Publication of the Association of American Feed Control Officials. See the pages and sections indicated below:

Glutamic acid solubles, see page 237, section 36.1.

yeast paste, yeast products are described on page 306, sections 96.2-96.10.

water absorbers, see pages 292-295.

direct fed/fed microbials, see page 239, section 36.14

mold inhibitors, chemical preservatives are described on page 215.

liquid feed products, pages 205-307 describe a variety of liquid feed products.

While some of these terms may be functionally defined, e.g. "mold inhibitor" or "water absorbers", they are not indefinite, as one with skill in the art would understand which feed additives would have these properties.

Moreover, undue experimentation would not be required to select an appropriate mold inhibitor or water absorber based on the level of skill in the art as shown by the attached document on feed ingredients.

Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection--35 U.S.C. 112, first paragraph

Claims 1-57 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate description. Applicants submit that this rejection may be withdrawn, as the specification

describes the interaction between phosphorous and a metal compound, as well as exemplifying it, see e.g. Examples 1 and 2 on pages 7 and 8 of the specification.

The rejection with respect to methods of treating urinary calculi or milk fever is moot in view of the cancellation of these claims.

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Rejection--35 U.S.C. 102

Claims 1, 2, 4, 6-8, 10, 12-15, 17, 19-21, 23, 25-27, 29, 31-33, 35 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Vinci et al., U.S. Patent No. 5,382,678. Vinci does not anticipate the invention, as Vinci only describes cottonseed meal (see col. 4) and does not disclose coating intact cottonseed.

Rejection--35 U.S.C. 103

Claims 1-57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, U.S. Patent No. 5,972,414, in view of Hamada et al., U.S. Patent 3,686,392, Schroeder et al., U.S. Patent No. 4,160,041 and Vinci et al., U.S. Patent No. 5,382,678. The cited art does not render the invention obvious, because it does not disclose or suggest coating and curing intact cottonseed with a mixture of a liquid feed product, soluble phosphorous and a metal.

Harris discloses treating whole cottonseed with an aqueous composition comprising either condensed whey solubles or condense molasses solubles, see col. 5, lines 1-7. Lines 8-11 describe adjusting the pH of these solutions using concentrated sulfuric acid or calcium hydroxide. The solutions are then sprayed on to whole cottonseed and dried. Harris does not suggest that the combination of soluble phosphorous and a metal, such as calcium, would form a coating, does not suggest that the addition of calcium hydroxide forms a cottonseed coating, and does not require a curing step to form a coating. Moreover, there is no suggestion in Harris to use glutamic acid fermentation solubles, see e.g. Claims 3 and 16.

Hamada does not disclose whole cottonseed, see col. 2, line 1, which refers to cottonseed meal. Moreover, there is no suggestion to coat intact cottonseed with a mixture of soluble phosphorous and a metal, such as calcium, or for a method which requires curing such a solution to form a coating on intact cottonseed to provide a coated product with improved characteristics, such as improved flowability, see e.g. Examples-1 and 2 in the specification.

Schroeder describes cottonseed meal, see col. 7, line 26, and “solid block” products, see col. 9, line 25, but does not disclose or suggest coating intact cottonseed. While this document is directed to a method for preparing solid animal feeds and describes an *in situ* reaction between a hydratable metal oxide such as calcium oxide and a water soluble phosphate, such as phosphoric acid, see abstract, there is no suggestion that these compounds would form a suitable coating on intact cottonseed, for instance, a coating that improves flowability of the resulting cottonseed product.

Vinci has been discussed above and does not disclose or suggest products involving intact cottonseed.

Accordingly, as none of the cited prior art disclose or suggest the intact coated cottonseed products of the invention, nor the coating methods used to produce these products, nor the improved properties of these products, such as improved flowability, the Applicants respectfully request that this rejection be withdrawn.

#### Rejection--Double Patenting

Claims 1-4, 6-17, 19-29, 31-39, 41-49, and 51-57 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-49 and 51-57 of copending U.S. Application No. 09/950,687. The Applicants thank the examiner for his suggestion about addressing this issue by filing a terminal

disclaimer and respectfully request that they be allowed to defer their response to this rejection until the identification of otherwise allowable subject matter.

**CONCLUSION**

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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# OFFICIAL NAMES AND DEFINITIONS OF FEED INGREDIENTS AS ESTABLISHED BY THE ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS

The bold print name and international feed name (IFN) are both acceptable feed names, unless designated otherwise in the definition.

Occasionally an item may be suggested as an ingredient in a mixed feed is not listed in this publication. When this happens, the appropriate investigator should be contacted, a term developed, and the product defined. Ingredients, e.g. sugar, are so common there is no need to define them.

## 3. ALFALFA PRODUCTS

Investigator and Section Editor--Stephen Kendall, OK

### Official

3.1 Suncured Alfalfa Meal, or Pellets or Ground Alfalfa Hay is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and stems, which has been suncured and finely ground. If it is chopped instead of finely ground, it must be designated as "Suncured Chopped Alfalfa" or "Chopped Alfalfa Hay." (Adopted prior to 1928, Amended 1937, 1965.)

IFN 1-00-104 Alfalfa hay suncured chopped  
IFN 1-00-090 Alfalfa hay suncured 13% Protein  
IFN 1-00-095 Alfalfa hay suncured 15% Protein  
IFN 1-00-096 Alfalfa hay suncured 17% Protein  
IFN 1-30-293 Alfalfa hay suncured 18% Protein  
IFN 1-00-088 Alfalfa hay suncured 20% Protein  
IFN 1-30-295 Alfalfa hay suncured 22% Protein  
IFN 1-00-111 Alfalfa hay suncured ground  
IFN 1-00-112 Alfalfa hay suncured ground 13% Protein  
IFN 1-00-113 Alfalfa hay suncured ground 15% Protein  
IFN 1-00-114 Alfalfa hay suncured ground 17% Protein  
IFN 1-30-296 Alfalfa hay suncured ground 18% Protein  
IFN 1-00-116 Alfalfa hay suncured ground 20% Protein  
IFN 1-00-117 Alfalfa hay suncured ground 22% Protein

2 Dehydrated Alfalfa Meal or Pellets is the aerial portion of the alfalfa reasonably free of other crop plants, weeds, and mold, which has been ground and dried by thermal means under controlled conditions other than sun curing. (Adopted 1928, Amended 1965, Amended 1995.)

IFN 1-00-025 Alfalfa Meal dehydrated  
IFN 1-00-021 Alfalfa Meal dehydrated 13% Protein  
IFN 1-00-022 Alfalfa Meal dehydrated 15% Protein  
IFN 1-00-023 Alfalfa Meal dehydrated 17% Protein  
IFN 1-30-297 Alfalfa Meal dehydrated 18% Protein  
IFN 1-00-024 Alfalfa Meal dehydrated 20% Protein  
IFN 1-07-851 Alfalfa Meal dehydrated 22% Protein

NOTE 1: The following guarantees are recommended for the various types of alfalfa meal and ground alfalfa hay:

or 15% Crude Protein, Crude Fiber not more than 30%  
or 17% Crude Protein, Crude Fiber not more than 27%  
or 18% Crude Protein, Crude Fiber not more than 25%  
or 20% Crude Protein, Crude Fiber not more than 22%  
or 22% Crude Protein, Crude Fiber not more than 20%

NOTE 2: A guarantee of the beta carotene content of alfalfa products expressed in milligrams per pound, and accompanied by an expiration date may be included on the label if the distributor so desires.

Guarantees made on the label (including the invoice), on the delivery ticket, on a "certificate of analysis", or other document associated with the distribution of an alfalfa product are to be in terms of milligrams per pound of beta carotene without reference to quantity of Vitamin A which may be derived therefrom by the animal.

Example: Beta carotene 60 milligrams per pound (a source of Vitamin A) (Adopted 1941, Amended 1945 and 1966.)

NOTE 3: Brand names, such as "Doe's \_\_\_\_\_% Alfalfa Meal with Animal Fat or Vegetable Oil", must be used to show that the product is a mixture and not simply alfalfa meal. The chemical name of the antioxidant or antioxidants must be listed in the ingredient statement. (Adopted 1963.)

3.3 Alfalfa Nutrient Concentrate is the product obtained from the extracted juice of freshly cut alfalfa, by coagulation, separation from the alfalfa solubles and subsequent dehydration. The product should express both protein and Xanthophyll guarantees. (Proposed 1982, Adopted 1983)

IFN 4-16-026 Alfalfa nutrient concentrate dehydrated.

3.4 Concentrated Alfalfa Solubles is the product obtained by the concentration of the liquid remaining after the separation of Alfalfa Nutrient Concentrate from the juice of freshly cut alfalfa. The moisture level should not exceed 50%. (Proposed 1982, Adopted 1983)

IFN 4-16-027 Alfalfa solubles condensed.

## 6. AMINO ACIDS AND RELATED PRODUCTS

Investigator and Section Editor--Mika Alewynse, FDA

### Official

6.1 DL-Methionine Hydroxy Analogue Calcium is a product which contains a minimum of 97% racemic 2-hydroxy-4-methylthiobutyric acid calcium salt. The percentage of DL-Methionine Hydroxy Analogue Calcium must be guaranteed. The term Methionine Supplement may be used in the ingredient list on a feed tag to indicate the addition of DL-Methionine Hydroxy Analogue Calcium. (Adopted 1959, Amended 1974, 1978, 1989.) 21 CFR 582.5477 IFN 5-03-087 DL-Methionine Hydroxy Analogue Calcium

6.2 DL-Methionine is a product which contains a minimum of 99% racemic 2-amino-4-methylthiobutyric acid. The percentage of DL-Methionine must be guaranteed. The term Methionine Supplement may be used in the ingredient list on a feed tag to indicate the addition of DL-Methionine. (Adopted 1957, Amended 1975, 1978, 1989.) 21 CFR 582.5475

IFN 5-03-086 DL-Methionine

6.3 Glycine is a product which contains a minimum of 97% aminoacetic acid. The percentage of glycine must be guaranteed. (Adopted 1957.) 21 CFR 582.5049

IFN 5-02-127 Glycine

6.4 L-Lysine is a product which contains a minimum of 95% L-2,6-diaminohexanoic acid. The percentage of L-lysine must be guaranteed. (Proposed 1966, Adopted 1969, Amended 1975.) 21 CFR 582.5411

IFN 5-08-022 L-Lysine

## Tentative

1 L-Threonine is a product which contains a minimum of 95% L-2,3-hydroxybutyric acid. The percentage of L-threonine must be guaranteed. (Proposed 1967, Adopted 1969, Amended 1975.) 21 CFR 582.5881 N 5-08-092 L-Threonine

2 DL-Tryptophan is a product which contains a minimum of 97% racemic DL-(3-indolyl)-propionic acid. The percentage of DL-tryptophan must be guaranteed. (Proposed 1967, Adopted 1969, Amended 1975.) 21 CFR 582.5882 N 5-08-093 DL-Tryptophan

3 DL-Methionine Hydroxy Analogue is a product which contains a minimum of 88% racemic 2-hydroxy-4-methylthiobutyric acid. The percentage of methionine Hydroxy Analogue must be guaranteed. The term Methionine may be used in the ingredient list on a feed tag to indicate the presence of DL-Methionine Hydroxy Analogue. (Proposed 1980, Adopted 1985) 21 CFR 582.5477

4 N 5-30-281 DL-Methionine Hydroxy Analogue

5 DL-Methionine Sodium is a product which contains a minimum of 88% racemic 2-amino-methylthiobutyric acid sodium salt. The percentage of methionine must be guaranteed. The term Methionine Supplement may be used in the ingredient list on a feed tag to indicate the addition of DL-methionine sodium salt. (Proposed 1983, Amended 1989, Adopted 1990), N 5-16-730 DL-Methionine Sodium

6 L-Tryptophan is a product which contains a minimum of 97% L-2,3-(3-indolyl)-propionic acid. The percentage of L-tryptophan must be guaranteed. (Proposed 1985, Adopted 1987) 21 CFR 582.5915 N 5-18-776 L-Tryptophan

7 L-Lysine Monohydrochloride is a product which contains a minimum of 98% L-lysine monohydrochloride. The percentage of L-lysine must be guaranteed. (Adopted 1989)

8 N 5-19-118 L-Lysine Monohydrochloride

9 Taurine is a product which contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in the feed of growing chickens. It is added to complete feed so that the total taurine content does not exceed 0.054 percent of the feed. (Adopted 1989)

10 N 5-09-821 Taurine

11 L-Arginine is a product which contains a minimum of 98% L-2-amino-3-guanidinovaleric acid. The percentage of L-arginine must be guaranteed. 21 CFR 582.5145 (Adopted 1990)

12 N 5-32-043 L-Arginine

13 DL-Arginine is a product which contains a minimum of 98% racemic DL-2-amino-3-guanidinovaleric acid. The percentage of DL-arginine must be guaranteed. 21 CFR 582.5145 (Adopted 1990)

14 N 5-32-044 DL-Arginine

15 L-Tyrosine is a product which contains a minimum of 98% L-2-amino-3-(4-hydroxyphenyl) propionic acid. The percentage of L-tyrosine must be guaranteed. 21 CFR 582.5920 (Adopted 1990)

16 N 5-32-045 L-Tyrosine

17 1. Guarantees for amino acids should be expressed as percent on a dry basis.

18 2. Unless indicated otherwise, the amino acids defined above can be used in animal feed for nutritional purposes in accordance with good manufacturing or feeding practices.

## Tentative

T6.16 L-Lysine Liquid is a product that contains a minimum of 50% L-2,6-diaminohexanoic acid by weight in a water solution. The L-lysine content must not be less than 85% on a moisture-free basis. The percentage of L-lysine must be guaranteed. 21 CFR 582.5411 (Proposed 1999)

## 9. ANIMAL PRODUCTS

Investigator and Section Editor—Larry Blunt, IA

## Official

\*Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: "Do not feed to cattle or other ruminants".

\*9.2 Meat is the clean flesh derived from slaughtered mammals and is limited to that part of the striate muscle which is skeletal or that which is found in the tongue, in the diaphragm, in the heart, or in the esophagus; with or without the accompanying and overlying fat and the portions of the skin, sinew, nerve, and blood vessels which normally accompany the flesh. It shall be suitable for use in animal food. If it bears a name descriptive of its kind, it must correspond thereto. (Adopted 1938, Amended 1939, 1963.) IFN 5-00-394 Animal meat fresh

\*9.3 Meat by-products is the non-rendered, clean parts, other than meat, derived from slaughtered mammals. It includes, but is not limited to, lungs, spleen, kidneys, brain, livers, blood, bone, partially defatted low temperature fatty tissue, and stomachs and intestines freed of their contents. It does not include hair, horns, teeth and hoofs. It shall be suitable for use in animal food. If it bears name descriptive of its kind, it must correspond thereto. (Proposed 1973, Adopted 1974, Amended 1978)

IFN 5-00-395 Animal meat by-products fresh

\*9.7 Animal Liver if it bears a name descriptive of its kind, it must correspond thereto. Meat is obtained by drying and grinding liver from slaughtered mammals. (Adopted 1954.) IFN 5-00-389 Animal livers meal

9.10 Poultry By-Product Meal consists of the ground, rendered, clean parts of the carcasses of slaughtered poultry, such as necks, feet, undeveloped eggs, and intestines, exclusive of feathers, except in such amounts as might occur unavoidably in good processing practices. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P), and minimum and maximum calcium (Ca). The Calcium (Ca) level shall not exceed the actual level of phosphorus (P) by more than 2.2 times. (Proposed 1985, Adopted 1990)

IFN 5-03-798 Poultry by-product meal rendered.

9.11 Poultry Hatchery By-Product is a mixture of egg shells, infertile and unhatched eggs, and culled chicks which have been cooked, dried, and ground, with or without removal of part of the fat. (Adopted 1957.)

IFN 5-03-796 Poultry hatchery by-product meal

\*9.12 Dried Meat Solubles is obtained by drying the defatted water extract of the clean, wholesome parts of slaughtered animals prepared by steaming or hot water extraction. It must be designated according to its crude protein content which shall be no less than 70%. (Proposed 1961, Adopted 1962, Amended 1964, 1967.)



# d Ingredient Definitions

5-00-393 Animal meat solubles dehydrated

Poultry By-Products must consist of non-rendered clean parts of slaughtered poultry such as heads, feet, viscera, free from fecal and foreign matter except in such trace amounts as might occur in good factory practice. (Proposed 1963, Adopted 1964.)

5-03-800 Poultry by-product fresh

Hydrolyzed Poultry Feathers is the product resulting from the treatment pressure of clean, undecomposed feathers from slaughtered poultry, additives, and/or accelerators. Not less than 75% of its crude protein must be digestible by the pepsin digestibility method.\* (Proposed 1961, 1965.)

5-03-795 Poultry feathers meal hydrolyzed

Fleshings Hydrolysate is obtained by acid hydrolysis of the flesh or salted hides. It is defatted, strained, and neutralized. If evaporated solids, it shall be designated "Condensed Fleshings Hydrolysate." It shall contain a minimum crude protein and maximum salt guarantee. (Proposed 1968.) Reg. 573-200

5-08-094 Animal skin fleshings hydrolyzed rendered

Spray Dried Animal Blood Cells. Spray Dried Animal Blood Cells is a product obtained by spray drying red and white blood cells which have been separated from the plasma of clean, fresh, whole animal blood with only a minimum of plasma as might occur unavoidably in good processing practices. The cells are dried by spraying into a draft of warm, dry air which carries the blood to finely divided particles. The guaranteed analysis is: a minimum of 8 percent; a minimum crude protein of 90 percent; and a minimum solubility in water of 75 percent. If the product bears a name descriptive of its kind, origin, or composition, it must correspond thereto. (Proposed 1966, Adopted 1998)

Meat Meal is the rendered product from mammal tissues, exclusive of added blood, hair, hoof, horn, hide trimmings, manure, stomach and contents except in such amounts as may occur unavoidably in good processing practices. It shall not contain added extraneous materials not provided for in this definition. The Calcium (Ca) level shall not exceed the actual level of Phosphorus (P) by more than 2.2 times. It shall not contain more than 12% indigestible residue\* and not more than 9% of the crude protein in the meal shall be pepsin indigestible\*. The label shall include guarantees for crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto. (Proposed 1971, Adopted 1972, Amended 1985, Adopted 1993.)

5-00-385 Animal meat meal rendered.

Meat and Bone Meal is the rendered product from mammal tissues, exclusive of any added blood, hair, hoof, horn, hide trimmings, stomach and rumen contents, except in such amounts as may occur unavoidably in good processing practices. It shall not contain added extraneous materials not provided for in this definition. It shall contain a minimum of 12% Phosphorus (P) and the Calcium (Ca) level shall not be more than 2.2 times the actual Phosphorus (P) level. It shall not contain more than 12% indigestible residue\* and not more than 9% of the crude protein in the meal shall be pepsin indigestible\*. The label shall include guarantees for crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum Calcium (Ca). If it bears a name

description of its kind, composition or origin it must correspond thereto. (Proposed 1985, Amended 1992, Adopted 1994.)

5-00-388 Animal meat with bone rendered.

Animal By-Product Meal is the rendered product from animal tissues, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in good processing practices. It shall not contain added extraneous materials not provided for by this definition. This ingredient definition is intended to cover those individual rendered animal tissue products that cannot meet the criteria as set forth elsewhere in this section. This ingredient is not intended to be used to label a mixture of animal tissue products. (Proposed 1985, Amended 1992, Adopted 1993.)

5-08-786

Meat Meal Tankage is the rendered product from mammal tissues, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in processing factory practices. It may contain added blood or blood meal, however, it shall not contain any other added extraneous materials not provided for by this definition. The Calcium (Ca) level shall not exceed the actual level of Phosphorus (P) by more than 2.2 times. It shall not contain more than 12% pepsin indigestible residue\* and not more than 9% of the crude protein in the product shall be pepsin indigestible\*. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin it must correspond thereto. (Proposed 1985, Amended 1992, Adopted 1994.)

5-00-386 Animal tankage meal rendered.

Meat and Bone Meal Tankage is the rendered product from mammal tissues, including bone, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents except in such amounts as may occur unavoidably in good processing practices. It may contain added blood or blood meal, however, it shall not contain any added extraneous materials not provided for in this definition. It shall contain a minimum of 4.0% Phosphorus (P) and the Calcium (Ca) level shall not be more than 2.2 times the actual Phosphorus (P) level. It shall not contain more than 12% pepsin indigestible residue\* and not more than 9% of the crude protein in the product shall be pepsin indigestible\*. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin it must correspond thereto. (Proposed 1985, Adopted 1994.)

5-00-387 Animal tankage with bone rendered.

Hydrolyzed Hair is a product prepared from clean, undecomposed hair, by heat and pressure to produce a product suitable for animal feeding. Not less than 80% of its crude protein must be digestible by the pepsin digestibility method\* (Proposed 1968, Adopted 1970.)

5-08-997 Animal hair hydrolyzed

Hydrolyzed Leather Meal is produced from leather scrap that is treated with steam for not less than 33 minutes at a pressure not less than 125 pounds per square inch and further processed to contain not more than 10% moisture, not less than 60% crude protein, not more than 6% crude fiber, not more than 2.75% chromium, and with not less than 80% of its crude protein digestible by the pepsin digestibility method\*. Hydrolyzed leather meal may

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in livestock feeds as provided in food additive regulation 573.540 (1968, Adopted 1970.)

5-08-998 Animal leather meal hydrolyzed

**Spray Dried Animal Blood** is produced from clean, fresh animal exclusive of all extraneous material such as hair, stomach belching, urine, such traces as might occur unavoidably in good factory practice, is removed from the blood by a low temperature, evaporator under until it contains approximately 30% solids. It is then dried by spraying a fine stream of warm, dry air which reduces the blood to finely divided particles of maximum moisture of 8% and a minimum crude protein of 85%. It is designated according to its minimum water solubility. (Proposed 1972, Adopted 1976, Adopted 1978.)

5-00-381 Animal blood spray dehydrated

**Poultry** is the clean combination of flesh and skin with or without any bone, derived from the parts or whole carcasses of poultry or game birds, exclusive of feathers, heads, feet and entrails. It shall be for use in animal food. If it bears a name descriptive of its kind, it shall correspond thereto. If the bone has been removed, the process may be designated by use of the appropriate feed term. (Proposed 1978, Adopted 1995, Amended 1997)

**Hydrolyzed Whole Poultry** is the product resulting from the hydrolysis of whole carcasses of culled or dead, undecomposed, poultry including heads, feet, entrails, undeveloped eggs, blood and any other specific parts of the carcass. The product must be consistent with the actual product of whole poultry and must be free of added parts; including, but not limited to, entrails, blood or feathers. The poultry may be fermented as a part of the manufacturing process. The product shall be processed in such a fashion as to make it suitable for animal food, including heating (boiling at 212°F, or at sea level, for 30 minutes, or its equivalent, and agitated, except in cooking equipment). The product may be acid treated, be subsequently neutralized. If the product bears a name descriptive of its kind, the name must be designated thereto. (Proposed 1995, Adopted 1997)

**Hydrolyzed Poultry By-Products Aggregate** is the product resulting from the hydrolysis, heat treatment, or a combination thereof, of all by-products of poultry, clean and undecomposed, including such parts as heads, undeveloped eggs, intestines, feathers and blood. The parts may be fermented as a part of the manufacturing process. The product shall be processed in such a fashion as to make it suitable for animal food, including heating (boiling at 212°F, or 100°C at sea level for 30 minutes, or its equivalent, and agitated, except in cooking equipment). It may, if acid treated, be subsequently neutralized. If the product bears a name descriptive of its kind, the name must be designated thereto. (Proposed 1978, Adopted 1980, Amended 1995, Adopted 1997)

**Egg Shell Meal** is a mixture of egg shells, shell membranes and egg obtained by drying the residue from an egg breaking plant in a dehydrator at a product temperature of 180°F. It must be designated according to its crude protein and calcium content. (Prop. 1975, Adopted 1982)

6-26-004 Poultry egg shells meal

**Blood Meal** is produced from clean, fresh animal exclusive of all extraneous materials such as hair, stomach belchings, etc., except as might occur unavoidably in good processing practices. The material used must be listed as a part of the product name such as con-

ventional cooker dried, steamed or hydrolyzed. The product usually has a dark black like color and is rather insoluble in water. (Proposed 1975, Adopted 1979, Amended 1991, Adopted 1993.)

IFN 5-26-005 Animal blood meal conventional cooker dehydrated

IFN Number — Animal blood meal steamed dehydrated

IFN Number — Animal blood meal hydrolyzed dehydrated.

**9.62 Blood Meal, Flash Dried** is produced from clean, fresh animal blood, exclusive of all extraneous material such as hair, stomach belchings and urine except as might occur unavoidably in good manufacturing processes. A large portion of the moisture (water) is usually removed by a mechanical dewatering process or by condensing by cooking to a semi-solid state. The semi-solid blood mass is then transferred to a rapid drying facility where the more tightly bound water is rapidly removed. The minimum biological activity of lysine shall be 80%. (Proposed 1975, Adopted 1980.)

IFN 5-26-006 Animal blood meal flash dehydrated

**9.63 Blood Protein** is produced by quick freezing and/or transporting in a chilled state, clean, fresh, whole or dewatered animal blood exclusive of all extraneous material such as hair, stomach belchings and urine except as might occur unavoidably in good manufacturing processes. If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto. (Proposed 1975, Amended 1980, Adopted 1982, Amended 1993, Adopted 1994.)

IFN 5-25-007 Animal blood fresh

**\*9.65 Glandular Meal and Extracted Glandular Meal** is obtained by drying liver and other glandular tissues from slaughtered mammals. When a significant portion of the water soluble material has been removed, it may be called **Extracted Glandular Meal**. (Proposed 1979, Adopted 1980.)

IFN 5-12-247 Animal glands meal

IFN 5-30-080 Animal glands meal water extracted

**\*9.67 Unborn Calf Carcasses** is the product obtained from whole unborn carcasses taken from slaughtered cows at government inspected slaughter plants. The product is produced by grinding the whole unborn carcass, exclusive of calf hides. The product is denatured, fresh frozen and shall be suitable for use as an animal feed. (Proposed 1979, Adopted 1980.)

IFN 5-30-081 Cattle fetus carcass without skin fresh

**\*9.68 Animal Digest** is a material which results from chemical and/or enzymatic hydrolysis of clean and undecomposed animal tissue. The animal tissues used shall be exclusive of hair, horns, teeth, hooves and feathers, except in such trace amounts as might occur unavoidably in good factory practice and shall be suitable for animal feed. If it bears a name descriptive of its kind or flavor(s), it must correspond thereto. (Proposed 1981, Amended 1983, Adopted 1990) IFN 5-06-935 Animal Digest Condensed.

**\*9.69 Cooked Bone Marrow** is the soft material coming from the center of large bones, such as leg bones. This material, which is predominantly fat with some protein, must be separated from the bone material by cooking with steam. It shall not contain added extraneous materials not provided for by this definition except for small amount of tissue which may adhere to the bone unavoidably in good processing practice. The labeling of this product shall include, but is not limited to, guarantees for minimum crude protein and minimum crude fat. (Proposed 1988, Adopted 1992)

**\*9.70 Mechanically Separated Bone Marrow** is the soft material coming from the center of large bones, such as leg bones. This material, which is

## d Ingredient Definitions

antly fat with some protein, must be separated from the bone material  
ical separation. It shall not contain added extraneous materials not  
for by this definition except for small amount of tissue which may  
the bone unavoidably in good processing practice. The labeling of  
uct shall include, but is not limited to, guarantees for minimum crude  
and minimum crude fat. (Proposed 1988, Adopted 1992)

**Poultry Meal** is the dry rendered product from a combination of clean  
i skin with or without accompanying bone, derived from the parts of  
reasses of poultry or a combination thereof, exclusive of feathers, heads,  
entrails. It shall be suitable for use in animal food. If it bears a  
scriptive of its kind, it must correspond thereto. (Proposed 1988,  
(1992)

**Animal Plasma** is the product obtained by spray drying plasma which  
i separated away from the cellular matter (red and white blood cells)  
whole blood by chemical and mechanical processing. The protein portion  
product is primarily albumin, globulin, and fibrinogen type proteins.  
imum percent crude protein and the maximum percent ash must be  
ed on the label. If it bears a name descriptive of its kind, composition,  
i, it must correspond thereto. (Proposed 1990, Adopted 1993)

**Ensilaged Paunch Product** is a product composed of the contents of  
if cattle slaughtered at USDA inspected facilities. The moisture level  
ed to 50-68%. The product is then packed into an airtight environment,  
a silo, where it undergoes an acid fermentation that retards spoilage.  
iled product will have a Ph of 4.0 or less. (Proposed 1990, Adopted

**Egg Product** is product obtained from egg graders, egg breakers and/or  
y operations that is dehydrated, handled as liquid, or frozen. These  
labeled as per USDA regulations governing eggs and egg products  
Part 59). This product shall be free of shells or other non-egg materials  
in such amounts which might occur unavoidably in good processing  
s, and contain a maximum ash content of 6% on a dry matter basis.  
ied 1991, Adopted 1996).

**77 Stock** is obtained by steam cooking USDA edible, fresh, wholesome  
containing meat and muscle tissue at least 3 hours at a minimum tem-  
e of 180°F and then drying the extracted broth. It must be designated  
le and according to its crude protein content which shall not be less  
%. In order for a reconstituted product to be labeled as stock, the  
e-to-protein ratio must not exceed 135:1 (135 parts water to 1 part  
). If the product bears a name descriptive of its kind, composition or  
it must correspond thereto. (Proposed 1993, Adopted 1994.)

**78 Meat Protein Isolate** is produced by separating meat protein from  
lean, unadulterated bones by heat processing followed by low temperature  
to preserve function and nutrition. This product is characterized by a  
teaty aroma, a 90% minimum protein level, 1% maximum fat and 2%  
um ash. (Proposed 1993, Adopted 1994.)

determined by AOAC method listed in the Check Sample Reference for  
ical Variations.

## Tentative

**20 Animal Serum.** Animal Serum is the product obtained by removing  
rin from liquid animal plasma by chemical and mechanical processes.  
um protein portion of this product is primarily albumin and globulin

proteins. The minimum percent crude protein, maximum percent ash, minimum  
albumin content, and the minimum globulin content must be guaranteed on  
the label. The minimum albumin content is 42% (as a percent of total protein)  
determined by colorimetric assay (Doumas, B.T., Watson, W.A., Biggs, H.G.,  
Clin. Chim Acta. 1971) and the minimum globulin content is 20% (As a percent  
of total protein) as measured by an assay method such as the Becker titer  
analysis (Becker, w. 1969 Immunochemistry 6: 539-546). If the product bears  
a name descriptive of its kind, origin or composition, it must correspond thereto.  
(Proposed 1996)

**T9.21 Serum Albumin.** Serum Albumin is the product obtained by removing  
the fibrin and globulin proteins from liquid animal plasma by chemical and  
mechanical processes. The resultant product will be greater than 60% albumin  
(as a percent of total protein) as measured by colorimetric assay (Doumas,  
B.T., Watson, W.A., Biggs, H.G., Clin Chim Acta. 1971). The minimum percent  
crude protein and the maximum percent ash must be guaranteed on the label  
as well as the minimum albumin concentration. If the product bears a name  
descriptive of its kind, origin or composition, it must correspond thereto. (Pro-  
posed 1996)

**T9.22 Serum Globulin.** Serum Globulin is the product obtained by removing  
the fibrin and albumin proteins from liquid animal plasma by chemical and  
mechanical processes. The resultant product will be greater than 40% globulin  
(as a percent of total protein) as measured by an assay method such as the  
Becker titer analysis (Becker, W. 1969 Immunochemistry 6: 539-546). The mini-  
mum percent crude protein and the maximum percent ash must be guaranteed  
on the label as well as the minimum globulin concentration. If the product  
bears a name descriptive of its kind, origin or composition, it must correspond  
thereto. (Proposed 1996)

**\*T9.77 Stock/Broth --** is obtained by cooking mammalian or poultry  
bones, parts, and/or muscle tissue. The crude protein content of stock/broth  
must be no less than 90% on a dry matter basis. In order for the stock/broth  
to be labeled as such, the moisture to crude protein ratio must not exceed  
135:1 (135 parts water to 1 part crude protein). The product must bear a name  
descriptive of its kind, composition or origin, such as, but not limited to, meat,  
beef, pork, poultry, chicken, turkey. (Proposed 1997)

**T9.75 Leather Hydrolysate** is obtained from chromium tanned unfinished  
leather shavings, trimmings, and/or lime fleshings that may or may not be pres-  
sure cooked with the addition of steam, sodium hydroxide, lime or magnesium  
oxide. Chromium is precipitated and separated so that only trivalent chromium  
at less than 1000 ppm on a dry matter basis remains in the hydrolysate. This  
product is available as a liquid ingredient or as a spray dried powder. In either  
form event, the analysis on a solids basis will not be less than 75% crude  
protein and not less than 85% of the protein shall be pepsin digestible\*. (Adopted  
1993, Amended 1999)

## 12. BARLEY PRODUCTS

Investigator and Section Editor--Ali Kashani, WA

## Official

12.1 Barley Hulls consist of the outer covering of the barley. (Adopted  
prior to 1928.)

IFN 1-00-496 Barley hulls

Feed Ingredient Definitions

2.3 Pearl Barley By-Product is the entire by-product resulting from the manufacture of pearl barley from clean barley. (Proposed 1961, Adopted 1962.)

5.00-548 Barley pearl by-product

2.4 Barley Mill By-Product is the entire residue from the milling of barley from clean barley and is composed of barley hulls and barley middlings. (Proposed 1961, Adopted 1962.)

FN 4.00-523 Barley mill run

15. BREWERS PRODUCTS

Investigator and Section Editor--Tony Claxton, MO

Official

15.1 Brewers Dried Grains is the dried extracted residue of barley malt or in mixture with other cereal grain or grain products resulting from manufacture of wort or beer and may contain pulverized dried spent hops in amount not to exceed 3%, evenly distributed. (Adopted 1965, Amended 1966.)

FN 5.00-516 Barley brewers grains dehydrated

15.2 Malt Sprouts is obtained from malted barley by the removal of the hulls and sprouts which may include some of the malt hulls, other parts of malt and foreign material unavoidably present. It must contain not less than 10% crude protein. The term malt sprouts when applied to a corresponding product of other malted cereals must be used in qualified form: i.e., "Rye Malt Sprouts", "Wheat Malt Sprouts", etc. (Adopted 1942, Amended 1964, 1980.)

FN 5.00-545 Barley malt sprouts dehydrated

FN 5.00-548 Rye malt sprouts dehydrated

FN 5.29-796 Wheat malt sprouts dehydrated

15.3 Malt Cleanings is obtained from the cleaning of malted barley or malted grain which does not meet the minimum crude protein standard of malt sprouts. It must be designated and sold according to its crude protein content. (Adopted 1942.)

FN 5.00-544 Barley malt cleanings dehydrated

15.4 Malt Hulls consists almost entirely of hulls as obtained in the cleaning of malted barley. (Adopted 1942.)

FN 1.00-497 Barley malt hulls

15.5 Dried Spent Hops is obtained by drying the material filtered from wort. (Adopted 1944.)

FN 5.02-396 Hop common fruit (hops) spent dehydrated.

15.6 Brewers Wet Grains is the extracted residue resulting from the manufacture of wort from barley malt alone or in mixture with other cereal grains and grain products. The guaranteed analysis shall include the maximum moisture. (Proposed 1971, Adopted 1974.)

FN 5.00-517 Barley brewers grains wet

15.7 Brewers Condensed Solubles is obtained by condensing liquids resulting from the manufacture of beer or wort. It must contain not less than 20% total solids, 70% carbohydrates on a dry matter basis and the guaranteed analysis shall include maximum moisture. (Proposed 1975.)

FN 5.12-239 Barley brewers soluble condensed

18. CHEMICAL PRESERVATIVES

Investigator and Section Editor--Joel Padmore, NC

Official

18.1 Chemical Preservatives	F.D.A. Regulations Additives Amendment	Classification Under Food Additives Amendment	Limitations or Restrictions
Name	Reg. 582.3013	Chemical Preservative	**None
Ascorbic acid	Reg. 582.3149	Chemical Preservative	**None
IFN 7.00-433			
Ascorbyl palmitate	Reg. 582.3021	Chemical Preservative	Not to exceed 0.1%
IFN 8.26-245			
Benzoic acid	Reg. 582.3169	Chemical Preservative	Total content of preservatives not more than 0.02% of fat or oil content, including essential (volatile) oil content of food.
IFN 8.26-244			
Butylated hydroxyanisole (BHA)*			
IFN 8.01-044			
Butylated hydroxytoluene (BHT)*	Reg. 582.3173	Chemical Preservative	**None
IFN 8.01-045			
Calcium ascorbate	Reg. 582.3189	Chemical Preservative	**None
IFN 8.26-246			
Calcium propionate	Reg. 582.3225	Chemical Preservative	**None
IFN 8.01-085			
Calcium sorbate	Reg. 582.6033	Chemical Preservative	**None
IFN 8.01-086			
Citric acid	Reg. 582.3280	Chemical Preservative	Total content of preservatives not more than 0.02% of fat or oil content, including essential (volatile) oil content of food.
IFN 8.01-233			
Dilauryl thiodipropionate	Reg. 582.3280	Chemical Preservative	Same as above
IFN 8.01-789			
Distearyl thiodipropionate	Reg. 582.3041	Chemical Preservative	**None
IFN 8.01-792			
Erythorbic acid	Reg. 573.380	Chemical Preservative	0.015% in or on feed
IFN 8.09-823			
Ethoxyquin	Reg. 573.480	Preservatives in hay crop silage	Not to exceed 2.25% of the silage (dry weight) or 0.45% (direct cut)
IFN 8.01-841			
Formic acid			
IFN 8.20-739			
Methylparaben	Reg. 582.3490	Chemical Preservative	0.1%

8-03-088 sodium bisulfite 8-26-302	Reg. 582.3616	Chemical Preservative	Not for use in meats or vitamin B1 sources	Tertiary butyl hydroquinone (TBHQ) IFN 8-04-829	I.R.P.***	Chemical Preservative	B1 sources Total content of preservatives not more than 0.02% of fat or oil content, including essential (volatile) oil content of food.
8-26-203 sodium metasilfite	Reg. 582.3637	Chemical Preservative	Not for use in meats or vitamin B1 sources **None	Thiodipropionic acid IFN 8-04-830	Reg. 582.3109	Chemical Preservative	Total contents of preservatives not more than 0.02% of fat or oil content, including essential (volatile) oil content of food.
8-03-761 sodium sorbate	Reg. 582.3640	Chemical Preservative	**None	Tocopherols IFN 7-05-038	Reg. 582.3890	Chemical Preservative	**None
8-02-807 sodium iononic acid	Reg. 582.3081	Chemical Preservative	Total content of preservatives not more than 0.02% of fat or oil content in including essential (volatile) oil content of food.				
8-03-308 ethyl gallate	Reg. 582.3660	Chemical Preservative	0.1%				
8-03-810 p-terphenylparaben	Reg. 582.3670	Chemical Preservative	0.1% (Equivalent preservative activity 0.01%) in edible fats or oils. **None				
8-03-909 ac gum	Reg. 582.3336	Chemical Preservative	0.1%				
8-26-304 sodium ascorbate	Reg. 582.3731	Chemical Preservative	Not for use in meats or vitamin B1 sources				
8-04-271 sodium benzoate	Reg. 582.3733	Chemical Preservative	Not for use in meats or vitamin B1 sources				
8-26-305 sodium bisulfite	Reg. 582.3739	Chemical Preservative	Not for use in meats or vitamin B1 sources 20 ppm (0.002%)				
8-26-306 sodium bisulfite	Reg. 582.3766	Chemical Preservative	**None				
8-04-283 sodium nitrite	Reg. 573.700	Preservative & color fixative in canned pet food containing fish, meat, and fish and meat by-products	**None				
8-04-289 sodium propionate	Reg. 582.3784	Chemical Preservative	**None				
8-04-290 sodium sorbate	Reg. 582.3795	Chemical Preservative	**None				
8-26-307 sodium sulfite	Reg. 582.3798	Chemical Preservative	Not for use in meats or vitamin B1 sources **None				
8-04-297 sodium bic acid	Reg. 582.3089	Chemical Preservative	Not to exceed 0.0015 as tin				
8-26-308 sodium chlorides	Reg. 582.3845	Chemical Preservative	Not for use in meats or vitamin B1 sources				
8-26-309 sodium fur dioxide	Reg. 582.3862	Chemical Preservative	Not for use in meats or vitamin B1 sources				

## 21. CITRUS PRODUCTS

Investigator and Section Editor--Stan Buscombe, CA

## Official

21.1 **Dried Citrus Pulp** is the ground peel, residue of the inside portions, and occasional cull fruits of the citrus family which have been dried, producing a coarse, flaky product. It may contain dried citrus meal or pellets and whole citrus seeds. If calcium oxide or calcium hydroxide is added as an aid in processing, the maximum percentage present, expressed as calcium (Ca), must be shown. If it bears a name descriptive of its kind or origin, it must correspond thereto. (Adopted 1958, Amended 1965.)

IFN 4-01-237 Citrus pomace without fines dehydrated (pulp)  
21.2 **Dried Citrus Meal** is the finer particles obtained by screening dried citrus pulp. (Adopted 1958, Amended 1965.)

IFN 4-01-235 Citrus pomace fines dehydrated (pulp)  
21.3 **Citrus Seed Meal, Mechanical Extracted**, is the seed or seed meals of orange and grapefruit from which most of the oil has been removed by means of pressure. It is composed mostly of the kernel with such portions of the hull and pulp as cannot be avoided in the manufacture of Citrus Seed Oil. It may be designated and sold according to its crude protein content. (Adopted 1958, Amended 1965.)

IFN 5-01-239 Citrus seeds meal mechanical extracted.

## 22. COLLECTIVE TERMS

Investigator and Section Editor--Larry Whitlock, TX

### Official

Collective terms recognize a general classification of ingredient origin, which perform a similar function, but do not imply equivalent nutritional values.

When a collective term is used, individual ingredients within that group cannot be listed on the label.

The control official shall be provided, upon request, the ingredients that are being used within each collective term by the manufacturer using collective terms.

#### 22.1 Animal Protein Products may include one or more of the following:

9.61	Animal Blood Dried	*9.40	Meat Meal
*9.42	Animal By-Product Meal	*9.50	Meat Meal Tankage
54.1	Buttermilk, Condensed	9.12	Meat Solubles, Dried
54.1	Buttermilk, Dried	54.18	Lactalbumin, Dried
54.16	Casein	54.19	Milk, Dried Whole
54.21	Casein, Dried Hydrolyzed	54.20	Milk Protein, Dried
54.17	Cheese Rind	9.14	Poultry By-Products
51.4	Crab Meal	9.10	Poultry By-Product Meal
51.10	Fish By-Products	9.11	Poultry Haichery By-Product
51.34	Fish Liver & Glandular Meal	51.5	Shrimp Meal
51.14	Fish Meal	54.4	Skimmed Milk, Condensed
51.9	Fish Protein Concentrate	54.6	Skimmed Milk, Cond. Cultured
51.24	Fish Residue Meal	54.3	Skimmed Milk, Dried
51.6	Fish Solubles, Condensed	54.5	Skimmed Milk, Dried Cultured
51.7	Fish Solubles, Dried	54.8	Whey, Condensed
*9.16	Fishings Hydrolysate	54.15	Whey, Condensed Cultured
*9.54	Hydrolyzed Hair	54.12	Whey, Condensed Hydrolyzed
*9.55	Hydrolyzed Leather Meal	54.7	Whey, Dried
9.59	Hydrolyzed Poultry By-Product Aggregate	54.11	Whey, Dried Hydrolyzed
9.15	Hydrolyzed Poultry Feathers	54.13	Whey-Product, Condensed
T9.75	Leather Hydrolysate	54.14	Whey-Product, Dried
*9.41	Meat & Bone Meal	54.10	Whey Solubles, Condensed
*9.51	Meat & Bone Meal Tankage	54.09	Whey Solubles, Dried

\*Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: "Do not feed to cattle or other ruminants".

#### 22.2 Forage Products may include one or more of the following:

3.2	Alfalfa Meal, Dehydrated	71.3	Flax Plant Product
3.1	Alfalfa Hay, Ground	60.11	Ground Grass
3.1	Alfalfa Meal, Suncured	45.1	Lespedeza Meal
60.27	Coastal Bermudagrass Hay	45.2	Lespedeza Stem Meal
48.20	Corn Plant, Dehydrated	84.2	Soybean Hay, Ground
60.20	Dehydrated Silage (Ensilage Pellets)		
22.3 Grain Products--In any of the normal forms such as whole, ground, cracked, screen cracked, flaked, kibbled, toasted, or heat processed:			
			Wheat
			Barley
48.3, 48.4, 48.5, 48.6	Corn	75.2, 75.4	Rice--Ground Brown,
48.11, 48.12, 48.19	(corn)	75.5	Ground Paddy, Ground Rough,

42.1, 42.6, 42.7  
69.6

Grain Sorghum  
Mixed Feed Oats  
Oats  
Triticale

Broken, or Chipped  
Rice, Brewers  
Rye

\* No official definition for the grain product.

#### 22.4 Plant Protein Products may include one or more of the following:

87.1	Algae Meal	84.12	Soy Protein Concentrate
60.34	Beans, Dried	84.4	Soybean Feed
71.77	Canola Meal	84.1	Soybeans, Ground
71.60, 71.61	Coconut Meal	84.7, 84.60, 84.61	Soybean Meal, Kibbled
24.30, 24.31	Cottonseed Flakes	84.13	Soybeans Heat Processed
24.2	Cottonseed Cake	84.11, 84.15	Soy Flour
24.10, 24.12	Cottonseed Meal	84.51	Soy Grits
24.50, 24.51	Cottonseed Meal, Low Gossypol	84.5	Sunflower Meal, Dehulled
24.4	Cottonseed, Whole Pressed	71.220, 71.221	Sunflower Meal, Dehulled
	Guar Meal	96.2	Yeast, Active Dry
60.18	Guar Meal	96.4	Yeast, Culture
71.1, 71.11	Linseed Meal	96.8	Yeast, Dried
71.9	Peanut Meal	96.1	Yeast, Primary Dried
	Peas	96.1	Yeast, Torula Dried
71.25	Rapeseed Meal	96.7	
71.130, 17.131	Safflower Meal		
22.5 Processed Grain By-Products may include one or more of the following:			
60.43	Aspirated Grain Fractions	48.16, 48.26	Hominy Feed
15.1	Brewers Dried Grains	15.2	Malt Sprouts
60.6	Buckwheat Middlings	69.1	Oat Groats
27.7	Condensed Distillers, Solubles	69.3	Oat Meal, Feeding
48.24	Condensed Fermented Corn	12.3	Pearl Barley By-Products
	Extractives w/ Germ Meal Bran	71.21	Peanut Skins
48.2	Corn Bran	75.3, 75.7	Rice Bran
48.8	Corn Flour	75.1	Rice Polishings
48.22, 48.23	Corn Germ Meal (Wet & Dry Milled)	78.2	Rye Middlings
48.13	Corn Gluten Feed	42.8	Sorghum Grain Flour, Partially Gelatinized
48.14	Corn Gluten Meal	42.9	Sorghum Grain Flour, Partially Aspirated, Gelat.
48.7	Corn Grits	93.1	Wheat Bran
27.5	Distillers Dried Grains/ Solubles	93.2	Wheat Flour
27.6	Distillers Dried Grains/ Solubles	93.6	Wheat Shorts
27.4	Distillers Dried Solubles	93.3	Wheat Germ Meal
	Flour	93.8	Wheat Germ Meal, Defatted
42.4	Grain Sorghum Germ Cake	93.5	Wheat Middlings
42.4	Grain Sorghum Germ Meal	93.4	Wheat Mill Run
42.7	Grain Sorghum Grits	93.7	Wheat Red Dog
42.10	Grain Sorghum Mill Feed		
* Should designate type of grain with flour.			
22.6 Roughage Products may include one or more of the following:			
60.7	Almond Hulls, Ground	60.84	Hulls
60.2	Apple Pectin Pulp, Dried	15.4	Malt Hulls
60.1	Apple Pomace, Dried	69.4	Oat Mill By-Product, Clipped
60.26	Bagasse	69.2	Oat Hulls
12.1	Barley Hulls	69.7	Oat Mill By-Product

- 12.4 Barley Mill By-Product  
60.36 Beet Pulp, Dried  
60.17 Buckwheat Hulls  
21.2 Citrus Meal, Dried  
21.1 Citrus Pulp, Dried  
21.3 Citrus Seed Meal  
48.1, 48.21 Corn Cob Fractions  
24.6 Cottonseed Hulls  
71.4 Flax Straw By-Products
- 71.6 Peanut Hulls  
75.6 Rice Hulls  
75.8 Rice Mill By-Product  
78.1 Rye Mill Run  
84.3 Soybean Hulls  
84.8 Soybean Mill Feed  
84.9 Soybean Mill Run  
71.23 Sunflower Hulls  
60.10 Straw, Ground  
60.8 Tomato Pomace, Dried
- \*22.7 Molasses Products may include one or more of the following:  
36.10 Beet Molasses  
63.1 Beet Molasses, Dried Product  
60.39 Beet Pulp, Dried, Molasses  
63.7 Cane Molasses  
63.3 Citrus Molasses  
96.9 Molasses Yeast Condensed Solubles
- \* The molasses collective term is not recognized by FDA (21 CFR 501.110)

24. COTTONSEED PRODUCTS  
Investigator and Section Editor--Stan Buscombe, CA  
Official

24.14 Ammoniated Cottonseed Meal is obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached. It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 20% of the total ration.

The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

- (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.
- (3) Directions for use to provide not more than 20% of the additive in the total ration and a prominent statement: "Warning--This feed should be used only in accordance with the directions furnished on the label."

(Reg. 573.140) (Proposed 1969, Adopted 1970.)  
IFN 5-09-352 Cotton seeds meal solvent extracted ammoniated

24.10 Cottonseed Meal, Mechanical Extracted, is the product obtained by finely grinding the cake which remains after removal of most of the oil from cottonseed by a mechanical extraction process. It must contain not less than 36% crude protein. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-625 Cotton seeds meal mechanical extracted 36% protein.  
24.12 Cottonseed Meal, Solvent Extracted, is the product obtained by finely grinding the flakes which remain after removal of most of the oil from cottonseed by a solvent extraction process. It must contain not less than 36% crude protein. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-632 Cotton seeds meal solvent extracted 36% protein  
24.2 Cottonseed Cake, Mechanical Extracted, is the unground product composed of the kernel and such portions of the lint, hull, and oil as remain after removal of most of the oil from cottonseed by a mechanical process. It must contain not less than 36% crude protein. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-623 Cotton seeds mechanical extracted caked 36% protein  
24.30 Cottonseed Flakes, Mechanical Extracted, is the unground product composed of the kernel and such portions of the lint, hull, and oil as remain after removal of the oil from cottonseed by a mechanical extraction process. It must contain not less than 36% crude protein. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-08-820 Cotton seeds mechanical extracted flaked 36% protein  
24.31 Cottonseed Flakes, Solvent Extracted, is the unground product composed of the kernel and such portions of the lint, hull, and oil as remain after removal of the oil from cottonseed by a solvent extraction process. It must contain not less than 36% crude protein. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-629 Cotton seeds solvent extracted flaked 36% protein  
NOTE: The following levels of minimum crude fat and maximum crude fiber are adopted for cottonseed meals, cake, or flakes, of respective grade.

--Crude Fat--			
Crude Protein	Mechanical	Solvent	Crude Fiber
36%	2.0%	0.5%	17%
41%	2.0%	0.5%	14%
43%	2.0%	0.5%	13%

IFN 5-01-617 Cotton seeds meal mechanical extracted 41% protein  
IFN 5-01-627 Cotton seeds meal mechanical extracted 43% protein  
IFN 5-01-621 Cotton seeds meal solvent extracted 41% protein  
IFN 5-01-630 Cotton seeds meal solvent extracted 43% protein

This product (when sold or distributed singly) may be additionally labeled with the following bold face terms when the requirements thereafter are met; \_\_\_\_\_ Prime Quality must be free of mold, excess lint, and sour, musty, or burnt odors.

\_\_\_\_\_, Off Quality shall be that which does not meet the prime quality requirements.

24.4 Whole-Pressed Cottonseed, Mechanical Extracted, is composed of sound, mature, clean, delinted, and unhulled cottonseed, from which most of the oil has been removed by mechanical pressure. It must be designated and sold by its crude protein content. If ground, it must be so designated. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-609 Cotton seeds meal mechanical extracted

24.50 Low Gossypol Cottonseed Meal, Mechanical Extracted, is a meal in which the gossypol is not more than 0.04% free gossypol. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-09-002 Cotton seeds low gossypol meal mechanical extracted



## 27. DISTILLERS PRODUCTS

Investigator and Section Editor—Jimmy Hopper, TN

## Official

27.1 **Molasses Distillers Dried Solubles** is obtained by drying the residue from the yeast fermentation of molasses after the removal of the alcohol by distillation. (Adopted 1943, Amended 1944.)

IFN 4-04-698 Sugarcane molasses distillers solubles dehydrated

27.2 **Molasses Distillers Condensed Solubles** is obtained by condensing to a syrupy consistency the residue from the yeast fermentation of molasses after the removal of the alcohol by distillation. (Adopted 1946.)

IFN 4-04-697 Sugarcane molasses distillers solubles condensed

27.3 **Potato Distillers Dried Residue** is the dried product obtained after the manufacture of alcohol and distilled liquors from potatoes or from a mixture in which potatoes predominate. (Adopted 1947.)

IFN 5-03-773 Potato distillers residue dehydrated

27.4 **Distillers Dried Solubles** is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain mixture by condensing the thin stillage fraction and drying it by methods employed in the grain distilling industry. The predominating grain must be declared as the first word in the name. (Proposed 1963, Adopted 1964.)

IFN 5-00-520 Barley distillers solubles dehydrated

IFN 5-02-147 Cereals distillers solubles dehydrated

IFN 5-02-844 Maize distillers solubles dehydrated

IFN 5-04-026 Rye distillers solubles dehydrated

IFN 5-04-376 Sorghum distillers solubles dehydrated

IFN 5-05-195 Wheat distillers solubles dehydrated

27.5 **Distillers Dried Grains** is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by separating the resultant coarse grain fraction of the whole stillage and drying it by methods employed in the grain distilling industry. The predominating grain shall be declared as the first word in the name. (Proposed 1963, Adopted 1964.)

IFN 5-00-518 Barley distillers grains dehydrated

IFN 5-02-144 Cereals distillers grains dehydrated

IFN 5-02-842 Maize distillers grains dehydrated

IFN 5-04-023 Rye distillers grains dehydrated

IFN 5-04-374 Sorghum distillers grains dehydrated

IFN 5-05-193 Wheat distillers grains dehydrated

27.6 **Distillers Dried Grains with Solubles** is the product obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing and drying at least 3/4 of the solids of the resultant whole stillage by methods employed in the grain distilling industry. The predominating grain shall be declared as the first word in the name. (Proposed 1963, Adopted 1964.)

IFN 5-12-185 Barley distillers grains with solubles dehydrated

IFN 5-07-987 Cereals distillers grains with solubles dehydrated

IFN 5-02-843 Maize distillers grains with solubles dehydrated

24.51 **Low Gossypol Cottonseed Meal, Solvent Extracted**, is a meal in which the gossypol is not more than 0.04% free gossypol. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968.)

IFN 5-01-633 Cotton seeds low gossypol meal solvent extracted

24.6 **Cottonseed Hulls** consist primarily of the outer covering of the cottonseed. (Proposed 1964, Adopted 1966.)

IFN 1-01-599 Cotton hulls

24.7 **Cottonseed Screenings** is obtained in the commercial delinting and processing of cottonseeds for planting purposes. It consists of lint, stems, leaves, small and immature seeds, sand and/or dirt. It must contain a minimum of 12% crude protein and not more than 30% crude fiber. It must be labeled with minimum guarantees for crude protein and crude fat and maximum guarantees for crude fiber and ash. If it contains more than 6.5% ash, the words "sand" and/or "dirt" must appear in the product name. (Proposed 1980, Adopted 1983.)

IFN 4-12-023 Cotton seed screenings

24.8 **Cotton Plant By-Product** is the residue from the ginning of cotton. It consists of cotton burs, leaves, stems, lint, immature seeds, and sand and/or dirt. It shall not contain more than 38% crude fiber, nor more than 15% ash. It must be labeled with minimum guarantees for crude protein and crude fat and maximum guarantees for crude fiber and ash. If it contains more than 15.0% ash, the words "sand and/or dirt" must appear in the product name. (Proposed 1980, Adopted 1983, Amended 1984.)

IFN 1-08-413 Cotton gin by-product

## Tentative

T24.10 **Cottonseed Meal, Mechanical Extracted**, is the product obtained by finely grinding the cake which remains after removal of most of the oil from cottonseed by a mechanical extraction process. It must contain not less than 36% crude protein. It may contain an inert, non-toxic conditioning agent either nutritive or non-nutritive or any combination thereof, to reduce caking and improve flowability in an amount not to exceed that necessary to accomplish its intended effect and in no case exceed 0.5%. The name of the conditioning agent must be shown as an added ingredient. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1984.)

IFN 5-01-625 Cotton seeds meal mechanical extracted 36% protein. "To replace definition 24.10 if adopted"

T24.12 **Cottonseed Meal, Solvent Extracted**, is the product obtained by finely grinding the flakes which remain after removal of most of the oil from cottonseed by a solvent extraction process. It must contain not less than 36% crude protein. It may contain an inert, non-toxic conditioning agent either nutritive or non-nutritive or any combination thereof, to reduce caking and improve flowability in an amount not to exceed that necessary to accomplish its intended effect and in no case exceed 0.5%. The name of the conditioning agent must be shown as an added ingredient. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1984.)

IFN 5-01-632 Cotton seeds meal solvent extracted 36% protein "To replace definition 24.12 if adopted"





Classification/Name	Source Organism	Typical Substrate	Function	Current Supported Use
Lactase	<i>Aspergillus niger</i> , var. <i>Aspergillus oryzae</i> , var. <i>Candida pseudotropicalis</i> <i>Kluyveromyces marxianus</i> var. <i>lactis</i> (formerly <i>Saccharomyces</i> sp.)	lactose containing products and byproducts	hydrolyzes lactose to glucose and galactose	
beta-Mannanase	<i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> <i>Trichoderma longibrachiatum</i> (formerly <i>reesei</i> )	corn, soybean meal, guar meal, copra meal	hydrolyzes B-mannans, a component of hemicellulose	reduction in stickiness of excreta in poultry fed guar meal
Pectinase	<i>Aspergillus aculeatus</i> <i>Aspergillus niger</i> , var. <i>Rhizopus oryzae</i>	corn, wheat	breaks down pectin	
Pullulanase	<i>Bacillus acidopullulyticus</i> <i>Bacillus licheniformis</i> containing a <i>Bacillus dermatiformis</i> gene for pullulanase	see alpha-Amylase	hydrolyzes starch	
Xylanase	<i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> <i>Bacillus subtilis</i> , var. <i>Humicola insolens</i> <i>Penicillium funiculosum</i> <i>Trichoderma longibrachiatum</i> (formerly <i>reesei</i> )	corn, barley, rye, wheat, grain sorghum, urticale, oats	hydrolyzes xyans, a component of hemicellulose	reduction of digesta viscosity with poultry diets
Lipases	Animal pancreatic tissue <i>Aspergillus niger</i> , var. <i>Aspergillus oryzae</i> , var. <i>Candida rugosa</i> (formerly <i>cylindracea</i> ) <i>Rhizomucor (Mucor) miehei</i> <i>Rhizopus oryzae</i>	plant and animal sources of fats and oils	hydrolyzes triglycerides	

Classification/Name	Source Organism	Typical Substrate	Function	Current Supported Use
alpha-Galactosidase	<i>Aspergillus niger</i> , var. <i>Mortierella vinacea</i> var. <i>raffinoseutilizer</i> <i>Saccharomyces</i> sp.	sweet lupin, soybean meal	hydrolyzes oligosaccharides	
beta-Glucanase	<i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> <i>Bacillus subtilis</i> , var. <i>Humicola insolens</i> <i>Penicillium funiculosum</i> <i>Trichoderma longibrachiatum</i> (formerly <i>reesei</i> )	wheat, barley, canola meal, wheat byproduct, oat groats, rye, urticale, grain sorghum	hydrolysis of B-glucans, a polysaccharide type of non-starch	reduction of digesta viscosity with barley based poultry diets, reduces soluble non-starch polysaccharides in digesta
beta-Glucosidase	<i>Aspergillus niger</i> , var.	plant cell wall constituents	hydrolyzes cellulose to glucose	
Glucoamylase (Amyloglucosidase)	<i>Aspergillus niger</i> , var. <i>Aspergillus oryzae</i> , var. <i>Rhizopus niveus</i> <i>Rhizopus oryzae</i> , var.	see alpha-Amylase	hydrolyzes starch with production of glucose	
Hemicellulase	<i>Aspergillus aculeatus</i> <i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> <i>Bacillus subtilis</i> , var. <i>Humicola insolens</i> <i>Trichoderma longibrachiatum</i> (formerly <i>reesei</i> )	corn, soybean meal, guar meal, barley, rye, oat, peas, lentils	breaks down hemicellulose	reduction in stickiness of excreta in poultry fed guar meal
Invertase	<i>Aspergillus niger</i> , var. <i>Saccharomyces</i> sp.	sucrose containing products and byproducts	hydrolyzes sucrose to glucose and fructose	

# ENZYME MARKETING COORDINATION

**NOTE:** Sponsors of new enzyme/source organisms shall fully comply with this document by January 1, 1998.

## BACKGROUND

Enzymes are organic catalysts that affect the rate at which chemical reactions occur for specific substrates, including foods. AAFCO Policy Statement 7 describes the current sources of enzymes permitted in animal feeds. Rennet and papain are listed as GRAS under 21 CFR 582. All other enzyme materials to be used in animal feeds require a Food Additive regulation unless they are determined to be GRAS. The Center for Food Safety and Applied Nutrition (CFSAN) has published regulations for some enzyme preparations for use in human nutrition as secondary direct food additives under 21 CFR 173 and as GRAS food substances in 21 CFR 184. However, these applications are not directly transferable to animal use.

## DEFINITIONS

The terms presented below are to clarify this document and do not represent nomenclature utilized by all enzyme manufacturers.

**Enzyme.** A protein made up of amino acids or their derivatives, which catalyzes a defined chemical reaction. Required cofactors should be considered an integral part of the enzyme.

**Note:** All other organic catalysts are excluded from consideration under this marketing coordination scheme.

**Source organism.** The organism that actually produces the enzyme(s). **Manufacturer.** The firm or individual that actually produces the enzyme from the source organism.

**Sponsor.** The firm or individual that proposes adding an enzyme/source organism to the list published in the AAFCO Official Publication (Official Publication).

**Enzyme preparation.** A partially purified, unstandardized mixture of the enzyme(s) of interest and residues from the source organism. Enzyme preparations are not intended for sale or distribution for direct use on animal feed products without undergoing further processing.

**Enzyme containing material.** A material which is manufactured from the enzyme preparation, but is not necessarily, the final enzyme product. This material, if used in product development trials, must be substantially similar to the proposed product.

**Enzyme product.** A processed, standardized enzyme-containing material which has been produced with the intention of being sold for use on animal feed and feed ingredients. Examples of enzyme products would include feed grain treatments, commercial premixes and ready-to-use or apply materials. **Enzyme substrate.** The material or substance which is acted upon catalytically by the enzyme.

**Enzymatic activity (unit/L).** The catalytic activity required to convert a given amount of assay substrate to a given amount of product per unit time under the standard conditions set forth in the assay procedure.

## REGULATORY APPROACH

The U.S. Food and Drug Administration (FDA) considers all feed enzymes to be either food additives or GRAS substances as defined by the Federal Food, Drug, and Cosmetic Act. However, the FDA plans at the present time to utilize regulatory discretion in the regulation of feed enzymes that present no safety concerns. A food additive petition will not be required for many

This list is to provide guidance and is not all inclusive.

Classification/Name	Source Organism	Typical Substrate	Function	Current Supported Use
<b>Proteases</b>				
Bromelain	Pineapples - stem, fruit	plant and animal proteins	hydrolyzes proteins	
Ficin	Figs	plant and animal proteins	hydrolyzes proteins	
Papain	Papaya	plant and animal proteins	hydrolyzes proteins	
Pepsin	Porcine or other animal stomachs	plant and animal proteins	hydrolyzes proteins	
<b>Protease (general)</b>	<i>Aspergillus niger</i> , var.	plant and animal proteins	hydrolyzes proteins	
	<i>Aspergillus oryzae</i> , var.	plant and animal proteins	hydrolyzes proteins	
	<i>Bacillus amyloliquefaciens</i>	plant proteins	hydrolyzes proteins	
	<i>Bacillus subtilis</i> , var.	plant and animal proteins	hydrolyzes proteins	
	<i>Bacillus subtilis</i> containing a <i>Bacillus amyloliquefaciens</i> gene for protease	plant and animal proteins	hydrolyzes proteins	
<b>Trypsin</b>	Animal pancreas	plant and animal proteins	hydrolyzes proteins	
<b>Oxidoreductases</b>				
Catalase	<i>Aspergillus niger</i> , var.	hydrogen peroxide	produces water and oxygen from hydrogen peroxide	
	<i>Microcococcus lysodeikticus</i>	glucose	degrades glucose to hydrogen peroxide and gluconic acid	
<b>Glucose Oxidase</b>	<i>Aspergillus niger</i> , var.	glucose	hydrolyzes phytate	increases the digestibility of phytin-bound phosphorus in swine and poultry diets
<b>Phosphatases</b>	<i>Aspergillus niger</i> , var.	corn, soybean meal, sunflower meal, hominy, lupine, plant byproducts		
<b>Phytase</b>	<i>Aspergillus oryzae</i> , var.	corn, soybean meal, sunflower meal, hominy, lupine, plant byproducts		

Identity information should include the following:

- Active enzyme substance-- should be identified, preferably using the nomenclature system developed by the IUB. Specific terminology, such as "phosphatase, amylase or glucanase, are preferred.
- Enzyme substrate-- the specific substance on which the enzyme acts should be identified. General terminology such as carbohydrate, fiber, lipids, and protein are acceptable; however, specific terminology such as starch, cellulose, phytin, and lactose are preferred.
- Reaction products-- the primary resultant product(s) from the enzyme-substrate reaction should be identified to the extent that it is practical.
- Site of enzyme activity-- the site of activity is recognized to be on the feed/ingesta. Any other statement regarding site of activity is subject to FDA review.

#### BIOENGINEERED SOURCES OF ENZYMES

A source organism may be bioengineered using recombinant deoxyribonucleic acid (rDNA) technology. This type of technology is defined as "any method by which DNA is manipulated in vitro and introduced into the source organism." Initially, use of bioengineered source organisms will be handled on a case-by-case basis. If the structure/amino acid sequence of an enzyme has not been significantly affected by changes in the genome of the source organism, it is not anticipated that additional requirements will be imposed for inclusion in the Official Publication. However, if a source organism has been modified by rDNA techniques to contain an antibiotic resistance gene, then the enzyme product should contain no detectable, viable source organisms and no transmissible antibiotic resistance DNA.

#### SAFETY--Animal/Human/Environment

Safety is the overriding issue with food and food ingredients and thus, for enzyme/source materials for animal use. Initial questions will reside around whether the enzyme preparation has adverse effects on either the animal, the environment, or humans via edible products from animals fed the enzyme.

#### ANIMAL SAFETY

Enzymes, as defined in this document, are amino acid-based catalysts used at low levels to alter animal feedstuffs. Because of this basic structure, it is reasonable to assume that these molecules will be digested in the gastro-intestinal tract, as would any other protein. Since an enzyme will be broken down into its constituent amino acids and cofactors and thus, be indistinguishable from other food molecules, the potential for residues in edible animal tissues appears minimal. Thus, the only other major factor which may raise a safety concern is the possible presence of compounds produced by or derived from the source organism. Pariza and Foster (1983)<sup>1</sup> have developed a set of guidelines to assess the safety of enzymes used in food processing. These guidelines address the safety of the source organism and the enzyme itself. Enzyme preparations that meet or surpass the criteria proposed by Pariza and Foster for human food should be safe for use in animal feed when utilized at the low levels normally employed for these catalysts.

Alternatively, the sponsor can provide data demonstrating no adverse effects when the most sensitive target animal is fed at least 5 times the maximum supplementation level for a period of 90 days or 50% of the species normal growing period, whichever is less. The species will be determined by product labeling and/or manufacturer suggestions.

products. However, if the Agency has concerns about an enzyme/source organism, a formal food additive petition may be required.

This document, written jointly by the AAFCO, FDA, Agriculture and Agrifood Canada and industry, describes the information which may be necessary for confirmation of the suitability of an enzyme/source organism for inclusion in the Official Publication. Issuance of a favorable informal opinion by the FDA may provide the safety and functionality substantiation necessary for AAFCO to adopt an official definition for a food enzyme/source organism. All marketed enzymes must meet at least one of the following criteria: 1) be published in the Official Publication; 2) be the subject of a Food Additive regulation under 21 CFR 573; 3) be affirmed as GRAS; 4) be GRAS; or 5) be the subject of an informal no objection letter from the FDA (will be published in the next Official Publication). If an enzyme is published in the Code of Federal Regulations as an approved food additive it will also be included in the Official Publication. It should be noted that publication of an enzyme/source organism in the Official Publication does not remove a firm's responsibility of complying with applicable Canadian regulations.

The sponsor of an unpublished enzyme/source organism is to provide information which addresses issues of safety, functionality, labeling, and manufacturing. The request for review should be sent to the designated AAFCO contact. The supporting information should be sent to the Division of Animal Feeds, Center for Veterinary Medicine, FDA. The FDA will be asked to evaluate the information and determine its adequacy. If the FDA determines that the enzyme/source organism does not require an approved food additive petition to ensure its safe use, AAFCO will be asked to propose a new or modify an existing definition under which the enzyme/source organism would be published in the Official Publication. Any restrictions on claims and use conditions will be addressed by the FDA in its statements to AAFCO and the sponsor. The official definition will include: trivial name and/or International Union of Biochemistry (IUB) name, if available; enzyme classification; source organism; and substrate(s).

In the information package the sponsor may include material from the literature or current research. International data are acceptable provided conditions of testing simulate practices in this country. Supporting empirical information should be summarized and appropriate statistical analysis applied. Information that must be submitted by the sponsor includes: the sponsor's name and address, the enzyme, its proposed use and source organism. If any material written in a foreign language is included, a complete translation must be provided.

An appropriate section of the Official Publication is to be reserved for listing an enzyme and its source organism(s). After FDA evaluation of the information submitted for a new enzyme/source organism, a letter will be sent to the designated AAFCO contact. A copy of the letter will also be sent to the sponsor. Both the States and FDA will monitor the industry for compliance.

The following specific areas must be addressed by the sponsor:

#### ENZYME IDENTITY

The enzyme present in the enzyme preparation or product is to be identified and activity determined. The enzyme preparation or product is to be shown to contain no viable source organisms above an appropriate background. A suggested maximum is  $1 \times 10^4$  colony forming units (CFU/gram) of the source organism. If the source organism is published in the Official Publication under definition 36.14, there shall be no restriction on source organism numbers.

Enzyme sponsors should also address the presence of enzymatic cofactors in the enzyme preparation. The presence of cofactors, such as the vitamins or nicotinamide adenine dinucleotide (NAD) is not of concern, but should be reported. If the enzyme requires potentially toxic cofactors, such as selenium or molybdenum, the submission should indicate the identity and amount of the cofactor.

Enzymes produced using current good manufacturing practices from food animals, edible and nontoxic plants or nontoxic and nonpathogenic microorganisms which do not produce antibiotics, should be safe for consumption at the low levels one would normally expect to encounter in animal feeds. In addition, the enzyme preparation should comply with the chemical and microbiological purity standards established by the Joint FAO/WHO Expert Committee on Food Additives<sup>2</sup> and the Food Chemical Codex<sup>3</sup>.

Carriers, diluents, and processing aids used in the production of enzyme preparations and products must be substances that are acceptable for feed usage. If an enzyme preparation or product is standardized or diluted with feed grade material, then applicable chemical and microbiological standards for the feed material will apply.

#### HUMAN SAFETY

Enzymes, as defined in this document, are amino acid-based catalysts used at low levels to alter animal feedstuffs. Because of this basic structure, it is reasonable to assume that these molecules will be digested in the gastro-intestinal tract, as would any other protein. However, it is the responsibility of the sponsor to provide appropriate data to assure human safety. Enzymes used in animal feed that pass the safety assessment proposed by Pariza and Foster should raise no human safety concerns.

If the Pariza and Foster decision tree is not used to evaluate the enzyme preparation, the sponsor must provide information regarding the fate of the enzyme in the target animal. If it cannot be assured that the enzyme is broken down to non-toxic metabolites, it may be necessary to quantify the amount of residue and identify safety concerns for these molecules. If an enzyme preparation is currently approved for addition to or conditioning of human foods, human safety data may not be required. However, human food use must be substantiated and a statement of similar/identical usage will be required. If human food safety is an issue, a food additive petition under 21 CFR 570 will be required.

#### ENVIRONMENTAL SAFETY

Information is required on each enzyme/source organism to assure that it does not adversely affect the environment. Information showing that the enzyme is composed of or broken down to normal non-toxic degradation products in the digestive tract of supplemented animals would be adequate to answer questions of environmental safety. If degradation metabolites have an unusual chemical composition not normally present in foods, it may be necessary to demonstrate metabolite safety for non-target species that may be exposed if it could be demonstrated that the same or similar enzymes in approximately the same concentrations are excreted by free living organisms in a similar environment.

#### FUNCTIONALITY

The functionality of the enzyme itself must be documented. Either *in vivo* or *in vitro* data are acceptable to demonstrate enzyme functionality. The functionality statement associated with an enzyme/source organism combination will be determined by the data submitted under this proposal. The chosen

research approach, either *in vivo* or *in vitro*, should answer questions relating to the amount of enzyme material necessary to have the intended effect and the use conditions (restrictions) for the enzyme. All experimental protocols should be described as would be required for publication in a peer-review journal. The procedure used to determine enzyme functionality should be described in detail. If functionality is determined by end product measurements, assay sensitivity and cross-reactivity to other constituents/contaminants should be discussed. Functionality data must substantiate the proposed label. Animal experiments demonstrating enzyme functionality are highly recommended. Trial design should ensure that statistical analysis of experimental data is possible. The number of trials should be adequate to document enzyme functionality under field conditions. Indicators of enzyme functionality could include increased nutrient digestibility and/or increased free nutrient levels. Sponsors should note, however, that label/advertising claims for improved animal performance or health will cause an enzyme to be classified as a new animal drug.

Functionality can also be addressed using *in vitro* studies with either complete feeds, feed ingredients or feed substrates being utilized as the enzyme substrate. Experimental design and the accompanying statistical analysis must be adequate to support enzyme functionality under field conditions. Dependent on the reaction catalyzed, the sponsor may wish to measure the disappearance of undegraded feed substrate or the appearance of enzyme reaction products. This approach directly measures the enzymatic digestion of feedstuffs when compared to a similarly treated control sample. Either experimental approach is acceptable. However, the sponsor must explain how observed *in vitro* effects translate to practical functionality of the enzyme on feed or feed ingredients.

Factors which should be explained in detail in the submission include the apparatus/reagents/protocol used to conduct all functionality experiments. Buffer solutions should be selected so as to provide appropriate pH environments similar to those in which the enzyme product is expected to be used. All control (untreated) samples of feedstuffs shall be treated identically to the enzyme samples, except for the addition of the enzyme. Incubation temperatures for the digestion period should not exceed the range of temperatures normally encountered under practical conditions for enzyme use. The enzyme containing material may be either research or technical grade, but must be similar to that which will be used commercially.

Complete feeds, feed ingredients or feed substrates obtained from a feed ingredient, can be used to simulate the feed to which the enzyme will be applied. These experimental substrates should be similar in analysis and in physical/chemical treatment to the feed which the enzyme will be used for in commercial situations. No less than five samples of each grain/treatment should be used in the trial. Use of feed, feed ingredients or substrates containing grain from several different lots (origins) would be desirable. However, the experimental design should ensure that lots (origins) are not confounded with enzyme treatment, i.e. all of lot 1 treated with the enzyme, while all control samples came from a different lot.

#### Enzyme Functionality Tested by *in vitro* Activity on Feed

Collect samples of typical target feed or feed ingredient

Treat with candidate enzyme mixture for a given period of time at appropriate pH and temperature

Analyze samples for increased levels of breakdown products or decreased concentrations of targeted substrate

Compare results with untreated control samples. Enzyme treatments which result in significantly altered concentrations of targeted substrate or breakdown products are judged to be utilitarian for practical application.

#### QUANTIFICATION OF ENZYME PRODUCT

Methodology is needed to measure the amount of activity of the enzyme product in its marketed concentrated (premix) form. Activity should be expressed as micromoles (moles) of released catalytic product per minute per gram of market product or in other standardized units. It is the responsibility of the sponsor to provide this methodology along with supporting information about its specificity, sensitivity, and accuracy.

- a. Assay Methodology
  1. Enzyme product; and/or
  2. Finished feed
- b. Specificity/Sensitivity
  1. Two-external laboratory validation; or
  2. AOAC International validation, which can include the short form; or
  3. Other recognized methods

#### LABELING

The label should: describe the enzyme source (specific microbial or other source) that is recognized by FDA/AAFCO as safe and useful for the intended purpose; have a full listing of ingredients in order of preponderance; have a guaranteed analysis that is stated in meaningful terms; show a net quantity of product; contain warning and caution statements as needed; not have therapeutic or production claims; allow product identification by means such as lot numbers, expiration dates or another appropriate method of identification; and provide information on product storage, if necessary.

The product should be labeled in accordance with AAFCO and federal regulations. The label will include a guarantee of enzyme activity(ies), expressed in appropriate units. Clear directions for use which are reasonably certain to be followed in practice must be included, as should any known product limitations, such as ineffectiveness on specific forages. Adequate directions for use to enable the user to achieve the functionality of the enzyme(s) should be included, such as the feed ingredient(s) that the enzyme(s) acts on, the amount of product necessary to produce the intended effect, and the length of time required to achieve this effect. If environmental factors, such as feed pH or moisture, or mechanical processing methods, like pelleting or extrusion affect enzyme activity, these restrictions should also be noted on the label. Draft labeling should be included in the initial request of the sponsor.

The label must contain the following sections:

**Name of Product.**  
**Functionality Statement.** "Contains a source of \_\_\_\_\_ (enzymatic activity) which can \_\_\_\_\_ (function and/or current supported use as stated in Section 30.1)." (statement based on information present in submission)

**Guaranteed Analyses.** (see AAFCO regulations 3 and 4.)

Enzymatic guarantees shall be expressed in appropriate units using either metric or avoirdupois measurements. The chosen units shall correspond with those present in the Use section. The source organism for each type of enzymatic activity shall be specified, such as: Protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram.

If two sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided. However, the order of the ingredients in the Ingredients section is still determined by the amount (weight) of the different materials in the product.

**Ingredients.** (listed in order of predominance by weight)

**Directions for Use.** Use instructions shall clearly state amount of enzyme required to achieve intended effect and other necessary information required for enzyme functionality.

**Caution/Warning Statements.** (when required)

**Quantity Statement.**

#### MANUFACTURING

The sponsor is to provide information on the manufacture of the enzyme or quality controls (specifications) on the enzyme. The quality controls on the raw materials, on the manufacturing process/conditions, and on the enzyme product are to be presented. Appropriate information on product stability, labeling restrictions and special marketing controls are to be provided.

<sup>1</sup>Pariza, M.W. and E.M. Foster. 1983. Determining the safety of enzyme used in food processing. *Journal of Food Protection*. 46(5): 453-468.

<sup>2</sup>Joint FAO/WHO Expert Committee on Food Additives. 1990. General specifications for enzyme preparations used in food processing. *Food and Nutrition Paper No. 49*, Pages 80-93.

<sup>3</sup>Anonymous. 1980. *Food Chemical Codex*. Page 107. National Academy Press: Washington.

#### 33. FATS AND OILS

Investigator and Section Editor—Ricky Schroeder, TX

**NOTE:** The use of the term "feed grade" requires that the specific type of product be adequately tested to prove its safety for feeding purposes. In mixed feeds containing fats or fat derivatives the term "feed grade" may be omitted in the ingredient declaration.

**NOTE:** Any mixture of two or more fats or fat derivatives defined below is to be identified by listing each component: i.e., "animal fat and hydrolyzed vegetable oil."

**NOTE:** Fats or fat derivatives must come from acceptable animal feed sources. Waste water sludge that contains sanitary sewer water, is not an acceptable source of animal feed. FDA should be contacted regarding the safe use in animal feed of all other sludge material that does not contain sanitary waste water. (Sludge: The suspended or dissolved solid matter resulting from the processing of animal or plant tissue for human food. Waste Water Sludge: The sanitary sewer water and suspended or dissolved solid matter resulting from the processing of animal or plant tissues for human food.)

#### Official

**33.1 Animal Fat** is obtained from the tissues of mammals and/or poultry in the commercial processes of rendering or extracting. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its kind or origin; i.e., "beef", "poultry", it must correspond thereto. If

an antioxidant is used, the common name or names must be indicated, followed by the words "used as a preservative". (Proposed 1989)

#### IFN 4-00-409 Animal poultry fat

33.2 Vegetable Fat, or Oil is the product of vegetable origin obtained by extracting the oil from seeds or fruits which are commonly processed for edible purposes. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its kind or origin; i.e., "soybean oil", "cottonseed oil", it must correspond thereto. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative". (Proposed 1989)

#### IFN 4-05-077 Vegetable oil

33.3 Hydrolyzed Fat, or Oil, Feed Grade is obtained in the fat processing procedures commonly used in edible fat processing or soap making. It consists predominantly of fatty acids and must contain, and be guaranteed for, not less than 85% total fatty acids, not more than 6% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name; i.e., "hydrolyzed animal fat", "hydrolyzed vegetable fat", or "hydrolyzed animal and vegetable fat". If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative". (Proposed 1989)

#### IFN 4-00-376 Animal fat hydrolyzed, IFN 4-05-076 Vegetable oil hydrolyzed

33.4 Ester Feed Grade is the product consisting of methyl, ethyl, or other non-glyceride ester of fatty acids derived from animal and/or vegetable fats. It consists predominantly of the ester and must contain not less than 85% total fatty acids, not more than 10% free fatty acids, not more than 6% unsaponifiable matter (2% for methyl esters) and not more than 1% insoluble matter. Its source must be stated in the product name; i.e., "methyl ester of animal fatty acids", "ethyl ester of vegetable oil fatty acids". Methyl esters must contain not more than 150 parts per million (0.015%) free methyl alcohol. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "preservative(s)". (Proposed 1958, Amended 1962, Adopted 1968.) Reg. 573.640

#### IFN 4-00-377 Animal fatty acids of ethyl ester

#### IFN 4-00-378 Animal fatty acids of methyl ester

#### IFN 4-00-379 Animal fatty acids of non-glyceride ester

#### IFN 4-12-240 Vegetable fatty acids of ethyl ester

#### IFN 4-05-075 Vegetable fatty acids of non-glyceride ester

#### IFN 4-05-074 Vegetable fatty acids of methyl ester

33.5 Fat Product, Feed Grade is any fat product which does not meet the definitions for animal fat, vegetable fat or oil, hydrolyzed fat or fat ester. It must be sold on its individual specifications which will include the minimum percentage of total fatty acids, the maximum percentage of unsaponifiable matter, the maximum percentage of insoluble impurities, the maximum percentage of free fatty acids and moisture. The above listed specifications must be guaranteed on the label. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative". (Proposed 1989)

#### IFN 4-00-414 Animal vegetable fat product

33.6 Corn Endosperm Oil is obtained by the extraction of oil from corn gluten. It consists predominantly of free fatty acids and glycerides, and must contain not less than 85% total fatty acids, not more than 14% unsaponifiable

matter, and not more than 1% insoluble matter. If an antioxidant(s) is used, the common name or names must be indicated followed by the word "preservative(s)". (Proposed 1963, Adopted 1968.) Reg. 8.322

#### IFN 4-02-852 Maize endosperm oil

33.7 Vegetable Oil Refinery Lipid, Feed Grade. Vegetable Oil Refinery Lipid, Feed Grade is obtained in the alkaline refining of a vegetable oil for edible use. It consists predominantly of the salts of fatty acids, glycerides, and phosphates. It may contain water and not more than 22% ash on a water-free basis. It may or may not be acidulated before using in commercial feeds, but if acidulated, it should be neutralized. (Proposed 1964, Adopted 1968, Amended 1980, Amended 1996, Adopted 1999)

#### IFN 4-05-078 Vegetable oil refinery lipid

33.8 Corn Syrup Refinery Insolubles, Feed Grade is obtained in the refining of a corn syrup. It consists predominantly of the fatty fraction of corn starch together with protein and residual carbohydrate. It may contain water and not more than 7% ash nor less than 50% fat on a water-free basis. (Proposed 1964, Adopted 1968.)

#### IFN 4-02-893 Maize syrup process residue

33.14 Calcium Salts of Long-Chain Fatty Acids are the reaction products between calcium and long-chain fatty acids of vegetable and/or animal origin. They shall contain a maximum of 20% lipid not bound in the calcium salt form and the percent total fat shall be indicated. The unsaponifiable matter (exclusive of calcium salts) shall not exceed 4% and moisture shall not exceed 5%. If an antioxidant(s) is used, its common name(s) must be indicated on the label. Prior to conducting an assay for total fats, hydrolysis of the calcium salts should be performed to liberate the lipid fraction. (Adopted 1993)

#### 33.15 Hydrolyzed

Sucrose Polyesters, Feed Grade is the product resulting from the acid hydrolysis of sucrose polyesters, such as olestra, to make them digestible. It shall consist predominantly of fatty acids and contain, and be guaranteed for, not less than 85% total fatty acids, not more than 2% Sucrose Polyesters (hex ester and above), not more than 2% unsaponifiable matter, and not more than 2% insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name; i.e., "Hydrolyzed animal sucrose polyesters", "Hydrolyzed vegetable sucrose polyesters", or "Hydrolyzed animal and vegetable sucrose polyesters." If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." (Proposed 1993, Adopted 1994)

### 36. FERMENTATION PRODUCTS

Investigator and Section Editor—Fred Gatlin, KS

#### Official

36.1 Condensed, Extracted Glutamic Acid Fermentation Product is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of *Corynebacterium lilium* or *Corynebacterium glutamicum* used to produce the glutamic acid. (Proposed 1964, Adopted 1965, Amended 1995, Adopted 1997.) Reg. 573.500

#### IFN 5-01-595 Glutamic acid fermentation residue condensed

36.2 Extracted Presscake is the filtered and dried mycelium obtained from fermentation. (For label identification the source must be indicated as penicillium, streptomycetes, citric acid, etc.) (Adopted 1951.)

#### IFN 5-07-154 Penicillium fermentation presscake dehydrated

#### IFN 5-07-155 Streptomycetes fermentation presscake dehydrated

IFN 5-06-161 Enterococcus (formerly Streptococcus) faecium fermentation product liquid

Note: Dried Cultured Skimmed Milk--refer to 54.5 Milk Products Section. Condensed Cultured Skimmed Milk--refer to 54.6 Milk Products Section.

36.13 Extracted \_\_\_\_\_ meal is the ground \_\_\_\_\_ presscake, mycelium obtained from \_\_\_\_\_ fermentation. (For label identification the source must be indicated as penicillium, streptomycetes, or citric acid and must be stated as that in the second word of the name. The third word of the name is for the form of the ingredient, i.e. presscake, meal, or pellets.) (Proposed 1988, Adopted 1997)

IFN 5-07-154 Penicillium fermentation presscake dehydrated  
IFN 5-07-155 Streptomycetes fermentation presscake dehydrated  
IFN 5-07-156 Citric acid fermentation presscake dehydrated  
IFN 5-06-163 Penicillium fermentation presscake meal extracted  
IFN 5-06-164 Streptomycetes fermentation presscake meal extracted  
IFN 5-06-162 Citric acid fermentation presscake meal extracted

36.14 Direct-Fed Microorganisms-- The following microorganisms were reviewed by the Food and Drug Administration, Center for Veterinary Medicine and found to present no safety concerns when used in direct-fed microbial products:

- |                              |                                       |
|------------------------------|---------------------------------------|
| Aspergillus niger            | Lactobacillus curvatus                |
| Aspergillus oryzae           | Lactobacillus delbrueckii             |
| Bacillus coagulans           | Lactobacillus fermentum               |
| Bacillus lentus              | Lactobacillus helveticus              |
| Bacillus licheniformis       | Lactobacillus lactis                  |
| Bacillus pumilus             | Lactobacillus plantarum               |
| Bacillus subtilis            | Lactobacillus euriarii                |
| Bacteroides amylophilus      | Leuconostoc mesenteroides             |
| Bacteroides capillosus       | Pediococcus acidilactici              |
| Bacteroides ruminocola       | Pediococcus cerevisiae (damnosus) —   |
| Bacteroides suis             | Pediococcus pentosaceus               |
| Bifidobacterium adolescentis | Propionibacterium freudenreichii      |
| Bifidobacterium animalis     | Propionibacterium shermanii           |
| Bifidobacterium bifidum      | Saccharomyces cerevisiae              |
| Bifidobacterium infantis     | *Enterococcus cremoris                |
| Bifidobacterium longum       | *Enterococcus diacetylactis           |
| Bifidobacterium thermophilum | *Enterococcus faecium                 |
| Lactobacillus acidophilus    | *Enterococcus intermedium             |
| Lactobacillus brevis         | *Enterococcus lactis                  |
| Lactobacillus bulgaricus     | *Enterococcus thermophilus            |
| Lactobacillus casei          | Yeast (as defined elsewhere)          |
| Lactobacillus cellulosus     | *Formerly cataloged as Streptococcus. |

Tentative

T36.4 Dried Extracted \_\_\_\_\_ Fermentation Solubles is the dried extracted broth obtained from \_\_\_\_\_ fermentation. (For label identification the source must be indicated such as penicillium, streptomycetes, or citric acid, or as permitted by FDA.) (Proposed 1988, Amended 1992, Adopted 1997)

IFN 5-06-166 Penicillium fermentation solubles extracted dehydrated  
IFN 5-06-176 Streptomycetes fermentation solubles extracted dehydrated  
IFN 5-06-165 Citric acid fermentation solubles extracted dehydrated

IFN 5-07-156 Citric acid fermentation presscake dehydrated

36.3 Extracted \_\_\_\_\_ Meal is the ground \_\_\_\_\_ presscake. (For label identification the source must be indicated as penicillium, streptomycetes, citric acid, etc.) (Adopted 1951.)

IFN 5-06-163 Penicillium fermentation presscake meal extracted  
IFN 5-06-164 Streptomycetes fermentation presscake meal extracted  
IFN 5-06-162 Citric acid fermentation presscake meal extracted

36.10 Condensed \_\_\_\_\_ Fermentation Solubles is the product resulting from the removal of a considerable portion of the liquid by-product resulting from the action of the ferment on the basic medium of grain, molasses, whey, or other media. (For label identification, the source must be indicated as "Condensed (Whey, Grain, or Molasses) Fermentation Solubles." (Adopted 1958, Amended 1951, 1980.)

IFN 5-06-300 Cattle whey fermentation solubles condensed  
IFN 4-07-153 Cereals grain fermentation solubles condensed  
IFN 5-25-399 Sugarcane molasses fermentation solubles condensed

36.11 Dried \_\_\_\_\_ Fermentation Product is the product derived by culturing \_\_\_\_\_ on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, amino acids, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. If *Corynebacterium glutamicum* is used as a source of L-lysine, the label must provide a minimum guarantee for L-lysine and directions for use advising a maximum use limitation of 1% in the complete diet. (For label identification the source must be indicated such as B. subtilis, A. oryzae, A. niger, *Corynebacterium glutamicum*, Lactobacillus acidophilus, Lactobacillus bulgaricus or Streptococcus faecium, or as permitted by FDA.) (Proposed 1976, Adopted 1983, Amended 1997, Amended 1999.)

IFN 5-06-150 Bacillus subtilis fermentation product dehydrated  
IFN 5-06-151 Aspergillus niger fermentation product dehydrated  
IFN 5-06-152 Aspergillus oryzae fermentation product dehydrated  
IFN 5-06-153 Lactobacillus acidophilus fermentation product dehydrated  
IFN 5-06-154 Lactobacillus bulgaricus fermentation product dehydrated  
IFN 5-06-155 Enterococcus (formerly Streptococcus) faecium fermentation product dehydrated

36.12 Liquid \_\_\_\_\_ Fermentation Product is the liquid product derived by culturing or fermenting \_\_\_\_\_ on appropriate liquid nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and stabilized by approved methods in accordance with good manufacturing practices. Percent solids, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. (For label identification the source must be indicated such as B. subtilis, A. oryzae, A. niger, Lactobacillus acidophilus, Lactobacillus bulgaricus or Streptococcus faecium, or as permitted by FDA.) (Proposed 1976, Amended 1979, Adopted 1983, Amended 1997.)

IFN 5-06-156 Bacillus subtilis fermentation product liquid  
IFN 5-06-157 Aspergillus niger fermentation product liquid  
IFN 5-06-158 Aspergillus oryzae fermentation product liquid  
IFN 5-06-159 Lactobacillus acidophilus fermentation product liquid  
IFN 5-06-160 Lactobacillus bulgaricus fermentation product liquid

3-1-15



T36.6 Dried                      Fermentation Extract is the dried product resulting from extracting and precipitating by means of non-aqueous solvents or other suitable means, the water soluble materials from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism                      in accordance with good manufacturing practices. (For label identification the source must be indicated such as *B. subtilis*, *A. oryzae*, *A. Niger*, or as permitted by FDA.) (Proposed 1988, Amended 1992, Amended 1997)

IFN 5-06-147 *Bacillus subtilis* fermentation extract dehydrated  
IFN 5-06-148 *Aspergillus niger* fermentation extract dehydrated  
IFN 5-06-149 *Aspergillus oryzae* fermentation extract dehydrated  
T36.7 Dried                      Fermentation Solubles is the dried material resulting from drying the water soluble materials after separation of suspended solids from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism                      in accordance with good manufacturing practices. (For label identification the source must be indicated such as *B. subtilis*, *A. oryzae*, *A. niger*, or as permitted by FDA.) (Proposed 1988, Amended 1992, Amended 1997)

IFN Number 5-29-779 IFN Name *Bacillus subtilis* fermentation solubles dehydrated

IFN 5-29-781 *Aspergillus niger* fermentation solubles dehydrated  
IFN 5-29-780 *Aspergillus oryzae* fermentation solubles dehydrated

T36.9 Undried Extracted                      Solids and Fermentation Solubles is undried mycelium and extracted broth or the extracted and undried mycelium and broth obtained from                      fermentation. (For label identification the source must be indicated such as *penicillium*, *streptomyces*, *citric acid*, or as permitted by FDA.) (Proposed 1988, Amended 1997)

IFN 5-06-171 Citric acid fermentation solids with solubles liquid  
IFN 5-06-172 *Penicillium* fermentation solids with solubles liquid  
IFN 5-06-173 *Streptomyces* fermentation solids with solubles liquid

### 39. FLAX PRODUCTS

(See OTHER OILSEED PRODUCTS Section 71)

42. GRAIN SORGHUMS (MILO, HEGARI, KAFFIR, or FETERITA)  
Investigator and Section Editor--Roger Hoestenbach, TX

#### Official

42.1 Ground Grain Sorghum is the entire product made by grinding the grains of grain sorghum. (Adopted 1947, Amended 1962, 1964.)

IFN 4-04-379 Sorghum grain ground

IFN 4-04-378 Sorghum grain cracked

NOTE: The word "cracked" must be substituted for the word "ground" in the above definition when the product is cracked instead of ground.

42.2 Grain Sorghum Gluten Feed is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, by the processes employed in the wet milling manufacture of starch or syrup. (Adopted 1948, Amended 1950.)

IFN 5-04-389 Sorghum gluten with bran meal

42.3 Grain Sorghum Gluten Meal is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, and the separation of the bran by the processes employed in the wet milling manufacture of starch or syrup. (Adopted 1948, Amended 1950.)

IFN 5-04-388 Sorghum gluten meal

42.4 Grain Sorghum Germ Cake or Grain Sorghum Germ Meal consists of the germ of grain sorghum grains from which part of the oil has been pressed and is the product obtained in the wet milling process of manufacture of starch, syrup, and other grain sorghum products. (Adopted 1948, Amended 1950, 1960, 1963.)

IFN 5-04-377 Sorghum germs meal mechanical extracted

IFN 5-12-178 Sorghum germs mechanical extracted caked

42.6 Rolled Grain Sorghum is obtained by running whole grain sorghum over smooth flaking rolls, after properly tempering, removing most of the fine particles and subsequently dried and cooled. (Adopted 1953.)

IFN 4-04-380 Sorghum grain rolled

42.7 Grain Sorghum Grits consists of the hard flinty portions of sorghums containing little or no bran or germ. (Adopted 1959.)

IFN 4-04-384 Sorghum grits

42.8 Gelatinized Sorghum Grain Flour is obtained from the endosperm of sorghum grain which has been gelatinized and reduced to a finely ground meal and must contain not more than 1% crude fiber. (Proposed 1965, Adopted 1966.)

IFN 4-08-035 Sorghum flour gelatinized

42.9 Partially Aspirated Sorghum Grain Flour is obtained from whole sorghum grain which has been partially aspirated and has been gelatinized and reduced to a finely ground meal and must contain not more than 2.5% crude fiber. (Proposed 1965, Adopted 1966.)

IFN 4-08-036 Sorghum flour partially aspirated gelatinized

42.10 Grain Sorghum Mill Feed is a mixture of grain sorghum bran, grain sorghum germ, part of the starchy portion of grain sorghum kernels, or mixture thereof as produced in the manufacture of grain sorghum grits and refined meal and flour and must contain not less than 5% crude fat and not more than 6% crude fiber. (Proposed 1964, Adopted 1968.)

IFN 4-04-385 Sorghum grits by-product

NOTE: Any of the types shown parenthetically in the heading for this section may be substituted for the words "grain sorghums" in the above definitions. If the name of the type is given it must correspond thereto.

### 45. LESPEDEZA PRODUCTS

#### Official

45.1 Lespedeza Meal is obtained by grinding lespedeza hay which is reasonably free of other crop plants, weeds, and mold. It must not contain more than 28% crude fiber. (Adopted 1938, Amended 1963.)

IFN 1-02-523 Lespedeza hay sun-cured ground

45.2 Lespedeza Stem Meal is the ground product remaining after the separation of the leafy material from lespedeza hay or meal. It must be reasonably free from other crop plants and weeds. (Adopted 1938, Amended 1963.)

IFN 1-02-529 Lespedeza stems sun-cured ground

### 48. MAIZE

Investigator and Section Editor--Ken Jackson, NE

#### Official

48.1 Corn Cob Fractions is obtained by the mechanical separation of one or more fractions of corn cobs. For identification purposes the name of the fraction must be included parenthetically following the name of the product;

i.e., Corn Cob Fractions (Hard Woody Ring and Beeswings). (Proposed 1958, Adopted 1964.)

IFN 1-02-779 Maize cob fractions screened

48.2 Corn Bran is the outer coating of the corn kernel, with little or none of the starchy part of germ. (Adopted 1931.)  
IFN 4-02-841 Maize bran

48.3 Corn Feed Meal is the fine siftings obtained from screened cracked corn, with or without its aspiration products added. (Adopted 1941.)

IFN 4-02-880 Maize grain fines

48.4 Ground Corn is the entire corn kernel ground or chopped. It must contain not more than 4% foreign material. May also appear in the ingredient list of a mixed feed as Corn Meal or Corn Chop. (Adopted 1931.)

IFN 4-02-861 Maize grain ground

48.5 Cracked Corn is the entire corn kernel ground or chopped. It must contain not more than 4% foreign material. (Adopted 1931.)

IFN 4-02-854 Maize grain cracked

48.6 Screened Cracked Corn is the coarse portion of cracked corn from which most of the fine particles have been removed and may be fine, medium, or coarse. It must contain not more than 4% foreign material. (Adopted 1941.)

IFN 4-02-862 Maize grain cracked screened

48.7 Corn Grits is the medium sized hard flinty portions of ground corn containing little or none of the bran or germ. May also appear in the ingredient list of a mixed feed as Hominy Grits. (Adopted 1941.)

IFN 4-02-886 Maize grits

48.8 Corn Flour is the fine sized hard flinty portions of ground corn containing little or none of the bran or germ. (Adopted 1941, Amended 1960.)

IFN 4-08-024 Maize flour

48.9 Ground Ear Corn is the entire ear of corn ground, without husks, with no greater portion of cob than occurs in the ear corn in its natural state. May also appear in the ingredient list of a mixed feed as Corn and Cob Meal or Ear Corn Chop. (Adopted prior to 1928, Amended 1956.)

IFN 4-02-849 Maize ears ground

48.10 Ground Ear Corn with Husks is the entire ear of corn with husks ground or chopped, with not greater proportion of cob than occurs in the ear corn in its natural state. May also appear in the ingredient list of a mixed feed as Corn and Cob Meal with Husks, or Ear Corn Chop with Husks. (Adopted prior to 1928, Amended 1956.)

IFN 4-02-850 Maize ears with husks ground

48.11 Flaked Corn is obtained by running cracked corn which has been aspirated and properly tempered, over smooth flaking rolls and subsequently dried and cooled. (Adopted 1946.)

IFN 4-02-859 Maize grain flaked

48.12 Toasted Corn Flakes is obtained by running cracked corn which has been aspirated and properly tempered, over smooth flaking rolls, and subsequently dried, cooled, and toasted. (Adopted 1953.)

IFN 4-02-860 Maize grain flaked toasted

48.13 Corn Gluten Feed is that part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, gluten, and germ by the processes employed in the wet milling manufacture of corn starch

or syrup. It may or may not contain one or more of the following: fermented corn extractives, corn germ meal. (Adopted 1936, Amended 1960.)  
IFN 5-02-903 Maize gluten with bran

48.14 Corn Gluten Meal is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. (Adopted 1936, Amended 1960.)  
IFN 5-02-900 Maize gluten meal

48.16 Hominy Feed is a mixture of corn bran, corn germ, and part of the starchy portion of either white or yellow corn kernels or mixture thereof, as produced in the manufacture of pearl hominy, hominy grits, or table meal, and must contain not less than 4% crude fat. If prefixed with the words "white" or "yellow", the product must correspond thereto. (Adopted 1935.)

IFN 4-02-887 Maize grits by-product (Hominy Feed)

IFN 4-02-011 Maize dent yellow grits by-product (Hominy Feed)

IFN 4-02-990 Maize dent white grits by-product (Hominy Feed)

48.17 Dried Corn Syrup is a dried product from corn syrup, a purified concentrated aqueous solution of nutritive saccharides obtained from starch having a dextrose equivalent of 20 or more. (Proposed 1971, Adopted 1973.)  
IFN 4-02-892 Maize syrup dehydrated

48.18 Hydrolyzed Corn Protein is the product resulting from complete hydrolysis of isolated corn gluten, and after partial removal of the glutamic acid. (Adopted 1956.)

IFN 5-02-901 Maize gluten hydrolyzed

48.19 Kibbled Corn is obtained by cooking cracked corn under steam pressure and extruding from an expeller or other mechanical pressure device. (Adopted 1958.)

IFN 4-02-866 Maize grain kibbled

48.20 Dehydrated Corn Plant is the entire corn plant consisting of the ear, leaves, and stalk, which has been artificially dried and ground. (Adopted 1958.)

IFN 1-02-768 Maize aerial part dehydrated

48.21 Ground Corn Cob is the product resulting from grinding the entire cob. If it is designated as "Fine Ground", the entire grind must pass through a number 10 sieve and 33% of the total material must pass through a number 20 sieve. If it is designated "Coarse Ground", the entire grind must pass through a number four sieve and 50% must pass through a number 10 sieve. If it is designated as "Dehydrated", it must contain not more than 10% moisture. (Adopted 1958.)

IFN 1-02-780 Maize cobs dehydrated coarse ground

IFN 1-02-781 Maize cobs dehydrated fine ground

IFN 1-02-782 Maize cobs ground

48.22 Corn Germ Meal (Dry Milled) is ground corn germ which consists of corn germ with other parts of the corn kernel from which part of the oil has been removed and is the product obtained in the dry milling process of manufacture of corn meal, corn grits, hominy feed, and other corn products. (Definitions combined 1960.)

IFN 5-02-894 Maize germs meal dry milled mechanical extracted

48.23 Corn Germ Meal (Wet Milled) is ground corn germ from which most of the solubles have been removed by steeping and most of the oil removed by hydraulic, expeller, or solvent extraction processes, and is obtained in the

wet milling process of manufacture of corn starch, corn syrup, or other corn products. (Proposed 1960, Adopted 1961.)

IFN 5-02-897 Maize germs without extractives meal wet milled mechanical extracted

IFN 5-02-898 Maize germs without extractives meal wet milled solvent extracted

48.24 **Condensed Fermented Corn Extractives** is obtained by the partial removal of water from the liquid resulting from steeping corn in a water and sulphur dioxide solution which is allowed to ferment by the action of naturally occurring lactic acid producing microorganisms as practiced in the wet milling of corn. (Proposed 1959, Amended 1960, Adopted 1961.)

IFN 4-02-890 Maize extractives fermented condensed

48.25 **Maldextrins** is a purified concentrated aqueous solution of nutritive saccharides, or a dried product derived from said solution, derived from starch having a dextrose equivalent of less than 20. (Proposed 1971, Adopted 1973.)

IFN 4-08-023 Maize starch heat hydrolyzed

48.26 **Solvent Extracted Hominy Feed** is hominy feed from which the fat has been extracted by the solvent process. (Proposed 1965, Adopted 1966.)

IFN 4-08-025 Maize grits by-product solvent extracted (Hominy feed)

IFN 4-29-354 Maize grain heat processed

IFN 4-02-863 Maize grain heat processed flaked

IFN 4-02-864 Maize grain heat processed ground

IFN 4-02-865 Maize grain heat processed pelleted

#### Tentative

T48.30 **Liquidified Corn Product** is the product resulting from pressure hydrolysis of ground corn (steam cooking) and enzymatic treatment of the corn without removing any of the component parts. It shall contain not less than 30% solid. (Proposed 1978.)

IFN 4-28-211 Maize grain hydrolyzed liquid

T48.31 **Gelatinized Corn Flour** is obtained from endosperm of corn which has been gelatinized and reduced to a finely ground meal and must contain not more than 1% crude fiber. (Proposed 1978.)

IFN 4-07-022 Maize flour gelatinized

#### 51. MARINE PRODUCTS

Investigator and Section Editor—Teresa Crenshaw, DE

#### Official

51.14 **Fish Meal** is the clean, dried, ground tissue of undecomposed whole fish or fish cuttings, either or both, with or without the extraction of part of the oil. It must contain not more than 10% moisture. If it contains more than 3% salt (NaCl), the amount of salt must constitute a part of the brand name, provided that in no case must the salt content of this product exceed 7%. (Adopted 1933, Amend Amended 1984.)

IFN 5-01-977 Fish meal mechanical extracted

51.24 **Fish Residue Meal** is the clean, dried, undecomposed residue from the manufacture of glue from non-oily fish. If it contains more than 3% salt (NaCl), the amount of salt must constitute a part of the brand name, provided that in no case must the salt content of this product exceed 7%. (Adopted 1933.)

IFN 5-01-966 Fish glue residue meal

51.34 **Fish Liver and Glandular Meal** is obtained by drying the complete viscera of the fish. At least 50% of the dry weight of the product must be derived from fish liver and must contain at least 18 milligrams of riboflavin per pound. (Adopted 1944, Amended 1945.)

IFN 5-01-973 Fish viscera meal

51.4 **Crab Meal** is the undecomposed ground dried waste of the crab and contains the shell, viscera, and part or all of the flesh. It must contain not less than 25% crude protein. If it contains more than 3% salt (NaCl), the amount of salt must constitute a part of the brand name, provided that in no case must the salt content of this product exceed 7%. (Adopted 1933.)

IFN 5-01-663 Crab process residue meal

51.5 **Shrimp Meal** is the undecomposed ground dried waste of shrimp and contains parts and/or whole shrimp. If it contains more than 3% salt (NaCl), the amount of salt must constitute a part of the brand name, provided that in no case must the salt content of this product exceed 7%. (Adopted 1933, Amended 1963.)

IFN 5-04-226 Shrimp process residue meal

51.6 **Condensed Fish Solubles** is obtained by evaporating excess moisture from the stickwater, aqueous liquids, resulting from the wet rendering of fish into fish meal, with or without removal of part of the oil. Minimum percent of solids, minimum percent of crude protein, and minimum percent of crude fat must be guaranteed. (Proposed 1993, Adopted 1996)

51.7 **Dried Fish Solubles** is obtained by dehydrating the stickwater. It must contain not less than 60% crude protein. (Proposed 1963, Adopted 1964.)

IFN 5-01-971 Fish solubles dehydrated

51.8 **Fish Oil** is the oil from rendering whole fish or cannery waste. (Proposed 1963, Adopted 1964.)

IFN 7-01-965 Fish oil

51.9 **Fish Protein Concentrate—Feed Grade** is prepared from clean, undecomposed whole fish or fish cuttings using the solvent extraction process developed for the production of edible whole fish protein concentrate. It must contain not less than 70% protein and not more than 10% moisture. If the degree of fineness is stated, it must conform thereto. Solvent residues are not to exceed those established in Food Additive Regulations. (Proposed 1969, Adopted 1970, Amended 1971.) Reg. 573.440

IFN 5-09-334 Fish protein concentrate solvent extracted

51.10 **Fish By-products** must consist of non-rendered, clean undecomposed portions of fish (such as, but not limited to, heads, fins, tails, ends, skin, bone and viscera) which result from the fish processing industry. If it bears a name descriptive of its kinds, it must correspond thereto. Any single constituent used as such may be labeled according to the common or usual name of the particular portion used (such as fish heads, fish tails, etc). (Proposed 1974, Adopted 1975.)

IFN 5-14-509 Fish process residue fresh

51.11 **Dried Fish Protein Digest** is the dried enzymatic digest of clean undecomposed whole fish or fish cuttings using the enzyme hydrolysis process. The product must be free of bones, scales and undigested solids with or without the extraction of part of the oil. It must contain not less than 80% protein and not more than 10% moisture. If the degree of fineness is stated, it must conform thereto. (Proposed 1978, Adopted 1979)

IFN 5-18-778 Fish Protein hydrolyzed dehydrated

51.12 **Condensed Fish Protein Digest** is the condensed enzymatic digest of clean undecomposed whole fish or fish cuttings using the enzyme hydrolysis process. The product must be free of bones, scales, and undigested solids with or without the extraction of part of the oil. It must contain not less than 30% protein. (Proposed 1978, Adopted 1979.)

IFN 5-17-779 Fish Protein hydrolyzed condensed

51.13 **Fish Digest Residue** is the clean, dried, undecomposed residue (bones-scales-undigested solids) of the enzymatic digest resulting from the enzyme hydrolysis process of producing fish protein digest. It must be designated according to its protein, calcium and phosphorus content. (Proposed 1978, Adopted 1979.)

IFN 5-27-467 Fish Protein Residue hydrolyzed dehydrated

#### Tentative

T51.15 **Fish Stock/Broth** is obtained by cooking fish and/or other marine animal products, including bones, shells, parts, and/or muscle, but not including fish solubles. The crude protein content of the stock/broth base material must be no less than 90% on a dry matter basis. In order for the stock/broth to be labeled as such, the moisture-to-crude protein ratio must not exceed 135:1 (135 parts water to 1 part crude protein). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto. (Proposed 1999)

#### 54. MILK PRODUCTS

Investigator and Section Editor--Richard Uncles, NH.

##### Official

54.1 **Dried Buttermilk, Feed Grade** is the residue obtained by drying buttermilk. It contains 8% maximum moisture, 13% maximum ash, and 5% minimum milk fat (Roesse-Gottlieb method).\* (Adopted 1932, Amended 1964.)

IFN 5-01-160 Cattle buttermilk dehydrated

54.2 **Condensed Buttermilk** is the residue obtained by evaporating buttermilk. It contains 27% minimum total solids, 0.055% minimum milk fat for each % of total solids, and 0.14% maximum ash for each % of total solids. (Adopted prior to 1928, Amended 1944, 1964.)

IFN 5-01-159 Cattle buttermilk condensed

54.3 **Dried Skimmed Milk, Feed Grade**, is the residue obtained by drying defatted milk. It contains 8% maximum moisture.\* (Adopted 1930, Amended 1964.)

IFN 5-01-175 Cattle skim milk dehydrated

54.4 **Condensed Skimmed Milk** is the residue obtained by evaporating defatted milk. It contains 27% minimum total solids. (Adopted 1930, Amended 1964.)

IFN 5-01-172 Cattle skim milk condensed

54.5 **Dried Cultured Skim Milk** is the residue obtained by drying lactic acid bacteria cultured defatted milk. It contains 8% maximum moisture. (Adopted 1932, Amended 1964.)

IFN 5-01-174 Cattle skim milk cultured dehydrated

54.6 **Condensed Cultured Skim Milk** is the residue obtained by evaporating lactic acid bacteria cultured defatted milk. It contains 27% minimum total solids. (Adopted 1932, Amended 1964.)

IFN 5-01-173 Cattle skim milk cultured condensed

54.7 **Dried (Dry) Whey** is the product obtained by removing water from whey. It contains not less than 11 percent protein nor less than 61 percent lactose. (Adopted 1934, Amended 1948, 1950, 1951, 1964, 1981.)

IFN 4-01-182 Cattle whey dehydrated

54.8 **Condensed Whey** is the product obtained by partially removing water from whey. Minimum percent solids must be prominently declared on the label. (Adopted 1944, Amended 1951, 1963, 1964, 1982.)

IFN 4-01-180 Cattle whey condensed

54.9 **Dried (Dry) Whey Solubles** is obtained by drying the whey residue after removal of whey protein, with or without partial removal of lactose. Minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label. (Adopted 1944, Amended 1964, 1982.) IFN 4-01-189 Cattle whey solubles dehydrated

54.10 **Condensed Whey Solubles** is the product obtained by concentrating the whey residue after removal of whey protein, with or without partial removal of lactose. Minimum percent of solids, crude protein and lactose and maximum percent ash must be prominently declared on the label. (Adopted 1944, Amended 1964, 1982.)

IFN 4-01-188 Cattle whey solubles condensed

54.11 **Dried Hydrolyzed Whey** is the residue obtained by drying lactase enzyme hydrolyzed whey. It contains 30% minimum total glucose and galactose. (Adopted 1955, Amended 1964.)

IFN 4-01-184 Cattle whey hydrolyzed dehydrated

54.12 **Condensed Hydrolyzed Whey** is the residue obtained by evaporating lactase enzyme hydrolyzed whey. It contains 50% minimum total solids and 0.3% minimum total glucose and galactose for each percent total solids. (Adopted 1955, Amended 1964.)

IFN 4-01-183 Cattle whey hydrolyzed condensed

54.13 **Condensed Whey Product** is the product obtained by partially removing water from whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of solids, crude protein, and lactose and the maximum percent ash must be prominently declared on the label. May also be labeled "condensed reduced minerals whey" or "dried reduced minerals whey" or "condensed reduced lactose whey", if appropriate. (Adopted 1948, Amended 1964, 1982.)

IFN 4-01-185 Cattle whey low lactose condensed

54.14 **Dried (Dry) Whey Product** is the product obtained by drying whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label. May also be labeled as "dried reduced minerals whey" or "dried reduced lactose whey" if appropriate. (Adopted 1951, Amended 1952, 1964, 1982.)

IFN 4-01-186 Cattle whey low lactose dehydrated

54.15 **Condensed Cultured Whey** is the product obtained by partially removing water from whey which has been cultured. The minimum percent of solids must be prominently declared on the label. (Adopted 1949, Amended 1964.)

IFN 4-01-181 Cattle whey cultured condensed

54.16 **Casein** is the solid residue obtained by acid or rennet coagulation of defatted milk. It contains 80% minimum crude protein. (Adopted 1946, Amended 1964.)

IFNM 5-01-162 Casein acid precipitated dehydrated

54.17 Cheese Rind is obtained by cooking cheese trimming devoid of fat other than milk fat. (Adopted 1935, Amended 1964.)

IFN 5-01-163 Cheese rind  
54.18 Dried Lactalbumin is the dried coagulated protein residue from whey. It contains 80% minimum crude protein on a moisture free basis. (Adopted 1952, Amended 1964, 1989)

IFN 5-01-177 Cattle whey albumin

54.19 Dried Milk, Feed Grade is the residue obtained by drying whole milk or milk of intermediate fat levels other than defatted milk. If the product qualifies as dried whole milk by containing a minimum of 26% milk fat, that term may be used as the ingredient name. The label must contain a guarantee for minimum crude protein and for minimum crude fat (Roesse-Gottlieb method). \* (Adopted 1952, Amended 1964, 1995)

54.20 Dried Milk Protein is obtained by drying the coagulated protein residue resulting from the controlled co-precipitation of casein, lactalbumin, and minor milk proteins from defatted milk. (Proposed 1965, Adopted 1966.)

IFN 5-08-044 Cattle milk protein dehydrated

54.21 Dried Hydrolyzed Casein is the residue obtained by drying the water-soluble product resulting from the enzymatic digestion of casein. It contains 74% minimum crude protein. (Proposed 1966, Adopted 1967.)

IFN 5-08-055 Casein hydrolyzed dehydrated

54.22 Dairy Food By-Products are the products resulting from the collection of solids contained in the washwater from the normal processing and packaging of various foods manufacturing plants. Dairy products are the primary source but non-dairy products may occasionally constitute a minor amount of the total volume. No sanitary sewer wastes may be included. This product is to be fed at levels less than 25% of the animal's total dry matter intake. Minimum percent of solids, crude protein and crude fat and maximum percent ash must be prominently declared on the label. (Adopted 1982)

IFN 5-30-260 Cattle milk process residue

54.23 Condensed Modified Whey Solubles is the product obtained by concentrating the whey residue after removal of whey protein and partial removal of lactose, and modifying the sugar content so that there is a minimum of 0.3% nonlactose carbohydrate for each percent solids. The minimum percent of solids and the maximum percent ash must be prominently declared on the label. (Adopted 1982.)

IFN 4-01-188 Cattle whey solubles condensed

54.24 Whey is the product obtained as a fluid by separating the coagulum from milk, cream, or skimmed milk and from which a portion of the milk fat may have been removed. (Adopted 1982.)

IFN 4-08-134 Cattle whey fresh

54.25 Dried (Dry) Whey Protein Concentrate is the product obtained by removal or separation of water, lactose and/or minerals from whey by ultrafiltration, dehydration or other process. It shall contain 25% minimum crude protein. The minimum percent of crude protein and lactose and the maximum percent ash must be prominently declared on the label. (Adopted 1982.)

IFN 5-06-836 Cattle whey protein dehydrated

54.26 Dried Cultured Whey Product is that product obtained by drying whey from which a portion of the lactose, protein and/or minerals has been removed and which has been cultured. (Proposed 1988, Adopted 1989)

IFN 5-30-43 Cattle whey low lactose cultured dehydrated

54.27 Dried Cultured Whey is the product obtained by drying whey which has been cultured. The label shall include a guarantee for the minimum amount of lysine and methionine.

NOTE: This is the dried version of 54.15 condensed, cultured whey. AOAC HPLC methods are recommended to be used to quantitate the amino acids. (Proposed 1992, Adopted 1993)

54.28 Dried Chocolate Milk is the residue obtained by drying chocolate milk originally intended for human consumption. (Proposed 1992, Adopted 1993)

\* The words "feed grade" are not required when listed as an ingredient in a manufactured feed.

54.31 Dried Cheese is the product obtained by dehydrating cheeses as defined in 21 CFR, Part 133. No more than 10% of the fat may be other than milk fat. (Proposed 1992, Adopted 1999)

#### Tentative

T54.32 Dried Cheese Product is the product obtained by drying cheeses as defined in 21 CFR Part 133. No more than 25% of the fat may be other than milk fat. (Proposed 1992)

#### NOTES

## 57. MINERAL PRODUCTS

Investigator and Section Editor—Jim Balthrop, TX

(See Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients immediately following this section.)

\*Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: "Do not feed to cattle or other ruminants".

## Official

57.27 Ammonium Sulfate is the product resulting from the neutralization of sulfuric acid with ammonia. It shall contain not less than 21% nitrogen (N) and not less than 24% sulfur (S). It shall contain not more than 75 ppm arsenic (As) and 30 ppm heavy metals reported as lead. This does not include ammonium sulfate made from by-product ammonia recovered from coke-oven gas. It shall be used only in ruminant feeds as a source of sulfur and nitrogen in an amount that supplies not more than 2% of equivalent crude protein in the total daily ration. If a premix, concentrate, or supplement contains more than 2% of equivalent crude protein from ammonium sulfate, the label shall have adequate directions for use and a prominent statement, "Caution—This feed shall be used only in accordance with directions furnished on the label." (Proposed 1969, Adopted 1972.) Reg. 582.1143.

IFN 6-09-339 Ammonium sulfate

57.154 Basic Copper Chloride is the copper salt of hydrochloric acid and hydrated form of copper oxide generally expressed as  $\text{Cu}_2(\text{OH})_3\text{Cl}$  and its hydrated forms. Minimum copper (Cu) must be specified. (Proposed 1995, Adopted 1997)

57.1 Bone Ash is the ash obtained by burning bones with free access to air, and containing a minimum of 15.3% phosphorus (P). The label must show a guarantee for calcium (Ca) and phosphorus (P). (Adopted 1935, Amended 1952.) IFN 6-00-401 Animal bone ash.

57.2 Bone Charcoal is obtained by charring bones in closed retorts. It must contain a minimum of 14% phosphorus (P). It must be labeled with guarantees for calcium (Ca) and phosphorus (P). (This product is sometimes referred to as "Bone Black", however, bone charcoal must be used in all labeling.) (Adopted 1938, Amended 1952, 1963.)

IFN 6-00-402 Animal bone charcoal

57.17 Bone Charcoal, Spent, is the product resulting from the repeated charring of bone charcoal after use in clarifying sugar solutions. It must contain a minimum of 11.5% phosphorus (P). It must be labeled with guarantees for phosphorus (P) and calcium (Ca). (This product is sometimes referred to as "Spent Bone Black", however, spent bone charcoal must be used in all labeling.) (Adopted 1938, Amended 1952, 1963.)

IFN 6-00-404 Animal bone charcoal spent.

\*57.141 Bone Meal, Cooked, is the dried and ground sterilized product resulting from wet cooking without steam pressure of undecomposed bones. Fat, gelatin, and meat fiber may or may not be removed. When labeled as a commercial feed ingredient, it shall carry guarantees for protein, phosphorus (P), and calcium (Ca). Cooked bone meal shall be used in all labeling. (Proposed 1984)

IFN 6-17-171 Animal bone meal boiled.

\*57.18 Bone Meal, Steamed, is the dried and ground product sterilized by cooking undecomposed bones with steam under pressure. Grease, gelatin, and meat fiber may or may not be removed. It must be labeled with guarantees for phosphorus (P) and calcium (Ca). Steamed bone meal must be used in all labeling. (Proposed 1957, Adopted 1962, Amended 1964.)

IFN 6-00-400 Animal bone meal steamed

57.14 Bone Phosphate. Bone phosphate is the residue of bones that have been treated first in a hydrochloric acid solution and thereafter precipitated with lime and dried. It must contain a minimum of 17% phosphorus (P). It must be labeled with guarantees for calcium (Ca) and phosphorus (P). (Proposed 1952, Amended 1963, Amended 1997)

IFN 6-00-405 Animal bone phosphate

57.3 Calcite is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952.)

IFN 6-01-067 Calcite ground

57.10 Calcium Carbonate is a product true to name which contains a minimum of 38% calcium (Ca). (Adopted 1946, Amended 1963.) Reg. 582.5191.

IFN 6-01-069 Calcium carbonate

57.7 Calcium Carbonate, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Precipitated calcium carbonate must be used in all labeling. (Adopted 1952.)

IFN 6-01-071 Calcium carbonate, precipitated  $\text{CaCO}_3$ 

57.51 Calcium Chloride is the calcium salt of hydrochloric acid generally expressed as  $\text{CaCl}_2$  and its hydrated forms. Minimum calcium (Ca) and chlorine (Cl) must be specified. (Adopted 1975.)

IFN 6-20-774 Calcium chloride  $\text{CaCl}_2$ 

57.52 Calcium Gluconate is the calcium salt of gluconic acid generally expressed as  $\text{Ca}(\text{C}_6\text{H}_{11}\text{O}_7)_2$  and its hydrated forms. Minimum Calcium (Ca) must be specified. (Adopted 1975.)

IFN 6-01-073 Calcium gluconate monohydrate  $\text{Ca}(\text{C}_6\text{H}_{11}\text{O}_7)_2 \cdot \text{H}_2\text{O}$ 

57.53 Calcium Hydroxide is the hydrated form of calcium oxide generally expressed as  $\text{Ca}(\text{OH})_2$ . Minimum calcium (Ca) must be specified. (Adopted 1975.)

IFN 6-14-014 Calcium hydroxide  $\text{Ca}(\text{OH})_2$ 

57.54 Calcium Iodate is the calcium salt of iodic acid generally expressed as  $\text{Ca}(\text{IO}_3)_2$  and the monohydrate form. Minimum calcium (Ca) and iodine (I) must be specified. (Adopted 1975.)

IFN 6-01-075 Calcium iodate  $\text{Ca}(\text{IO}_3)_2 \cdot 6\text{H}_2\text{O}$ IFN 6-16-610 Calcium iodate monohydrate  $\text{Ca}(\text{IO}_3)_2 \cdot \text{H}_2\text{O}$ 

57.55 Calcium Iodobehenate is the calcium salt of iodohehonic acid generally expressed as  $\text{Ca}(\text{C}_{21}\text{H}_{42}\text{IO}_2)_2$  and its hydrated forms. Minimum calcium (Ca) and minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-01-077 Calcium iodobehenate  $\text{Ca}(\text{C}_{21}\text{H}_{42}\text{IO}_2)_2$ 

57.56 Calcium Oxide is the oxide form of calcium generally expressed as  $\text{CaO}$  (commonly called quicklime). The product of calcining limestone. A strong alkali requiring caution in its use. Minimum calcium (Ca) must be specified. (Adopted 1975.)

IFN 6-14-003 Calcium oxide  $\text{CaO}$ 

57.25 Calcium Periodate is an acceptable source of iodine. It is produced by reacting calcium iodate with calcium hydroxide or calcium oxide to form a

substance consisting of not less than 60% by weight of penta calcium orthophosphate containing 28 to 31% by weight of iodine. It is used or intended for use in salt for livestock as a source of iodine. Reg. 573.240 (Proposed 1969, Adopted 1971.)

IFN 6-09-355 Calcium periodate  $\text{Ca}_5(\text{IO}_6)_2$

57.57 Calcium Sulfate is the calcium salt of sulfuric acid generally expressed as  $\text{CaSO}_4$  and its hydrated forms. Minimum calcium (Ca) and minimum sulfur (S) must be specified. (Adopted 1975.)

IFN 6-01-087 Calcium sulfate anhydrous  $\text{CaSO}_4$

IFN 6-01-090 Calcium sulfate dihydrate  $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$

57.8 Chalk, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Precipitated chalk must be used in all labeling. (Adopted 1952.)

IFN 6-01-201, Chalk precipitated

57.6 Chalk Rock is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% of calcium (Ca). (Adopted 1952.)

IFN 6-01-202 Chalk rock ground

57.131 Clam Shells, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 35% calcium (Ca). (Proposed 1979, Adopted 1981.)

IFN 6-01-259 Clam shells ground

57.58 Cobalt Acetate is the cobalt salt of acetic acid generally expressed as  $\text{Co}(\text{C}_2\text{H}_3\text{O}_2)_2$  and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975.)

IFN 6-01-554 Cobalt acetate  $\text{Co}(\text{C}_2\text{H}_3\text{O}_2)_2$

57.59 Cobalt Carbonate is the cobalt salt of carbonic acid generally expressed as  $\text{CoCO}_3$  and its hydrated forms. Minimum Cobalt (Co) must be specified. (Adopted 1975.)

IFN 6-01-566 Cobalt carbonate  $\text{CoCO}_3$

57.60 Cobalt Chloride is the cobalt salt of hydrochloric acid generally expressed as  $\text{CoCl}_2$  and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975.)

IFN 6-01-556 Cobaltous chloride anhydrous  $\text{CoCl}_2$

57.123 Cobalt Choline Citrate Complex is the product resulting from the complexing of the soluble cobalt salt with choline dihydrogen citrate. Minimum cobalt (Co) must be specified. When used as a commercial feed ingredient, it must be declared as "cobalt choline citrate". (Proposed 1976.)

IFN 6-20-869 Cobalt choline citrate complex

57.148 Cobalt Glucoheptonate is the cobalt salt of glucoheptonic acid generally expressed as  $\text{C}_{14}\text{H}_{26}\text{O}_{16}\text{Co} \cdot \text{H}_2\text{O}$ . Minimum cobalt (Co) must be specified. (Proposed 1988, Adopted 1989)

IFN 6-19-211 Cobalt glucoheptonate

57.147 Cobalt Gluconate is the cobalt salt of gluconic acid, generally expressed as  $\text{Co}(\text{C}_6\text{H}_{11}\text{O}_7)_2$  and its hydrated forms. Minimum cobalt (Co) must be specified. (Proposed 1988, Adopted 1989)

IFN 6-19-210 Cobalt gluconate

57.61 Cobalt Oxide is the oxide form of cobalt generally expressed as  $\text{CoO}$ . Minimum cobalt (Co) must be specified. (Adopted 1975.)

IFN 6-01-560 Cobalt Oxide

57.62 Cobalt Sulfate is the cobalt salt of sulfuric acid generally expressed as  $\text{CoSO}_4$  and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975.)

IFN 6-01-562 Cobalt sulfate monohydrate  $\text{CoSO}_4 \cdot \text{H}_2\text{O}$

IFN 6-01-564 Cobalt sulfate heptahydrate  $\text{CoSO}_4 \cdot 7\text{H}_2\text{O}$

57.63 Copper Carbonate is the copper salt of carbonic acid generally expressed as  $\text{CuCO}_3$ . Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-703 Cupric carbonate  $\text{CuCO}_3$

57.64 Copper Chloride is the copper salt of hydrochloric acid generally expressed as  $\text{CuCl}$  or  $\text{CuCl}_2$  and their hydrated forms. Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-07-135 Cuprous chloride  $\text{CuCl}_2$

IFN 6-01-705 Cupric chloride dihydrate.  $\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$

57.122 Copper Choline Citrate Complex is the product resulting from the complexing of the soluble copper salt with choline dihydrogen citrate. Minimum copper (Cu) must be specified. When used as a commercial feed ingredient, it must be declared as "copper choline citrate". (Proposed 1976, Adopted 1977.)

IFN 6-20-868 Copper choline citrate complex

57.65 Copper Gluconate is the copper salt of gluconic acid generally expressed as  $\text{Cu}(\text{C}_6\text{H}_{11}\text{O}_7)_2$  and its hydrated forms. Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-707 Cupric gluconate  $\text{Cu}(\text{C}_6\text{H}_{11}\text{O}_7)_2$

57.66 Copper Hydroxide is the hydrated form of copper oxide generally expressed as  $\text{Cu}(\text{OH})_2$ . Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-709 Cupric hydroxide  $\text{Cu}(\text{OH})_2$

57.67 Copper Orthophosphate is the copper salt of phosphoric acid generally expressed as  $\text{Cu}_3(\text{PO}_4)_2$  and its hydrated forms. Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-713 Cupric orthophosphate  $\text{Cu}_3(\text{PO}_4)_2$

57.68 Copper Oxide is the oxide form of copper generally expressed as  $\text{CuO}$  or  $\text{Cu}_2\text{O}$ . Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-28-224 Cuprous oxide  $\text{Cu}_2\text{O}$

IFN 6-01-711 Cupric oxide  $\text{CuO}$

57.69 Copper Sulfate is the copper salt of sulfuric acid generally expressed as  $\text{CuSO}_4$  and its hydrated forms. Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-717 Cupric sulfate anhydrous  $\text{CuSO}_4$

IFN 6-01-719 Cupric sulfate pentahydrate  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$

57.70 Cuprous Iodide is the copper salt of hydriodic acid generally expressed as  $\text{CuI}$ . Minimum copper (Cu) must be specified. (Adopted 1975.)

IFN 6-01-721 Cuprous iodide  $\text{CuI}$

57.72 Diiodosalicylic Acid is an iodine compound of salicylic acid generally expressed as  $\text{C}_7\text{H}_4\text{I}_2\text{O}_3$ . Minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-01-787 Diiodosalicylic acid  $\text{C}_7\text{H}_4\text{I}_2\text{O}_3$

57.75 Ethylenediamine Dihydroiodide is an organic compound of iodine generally expressed as  $\text{C}_2\text{H}_8\text{N}_2\text{HI}$ . Minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-01-842 Ethylenediamine dihydroiodide  $\text{C}_2\text{H}_8\text{N}_2\text{HI}$

- 57.76 Ferric Ammonium Citrate is an ammoniacally complexed iron salt of citric acid of indefinite composition sometimes expressed as  $\text{Fe}(\text{NH}_4)_2\text{C}_6\text{H}_5\text{O}_7$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-857 Ferric ammonium citrate
- 57.78 Ferric Chloride is the iron salt of hydrochloric acid generally expressed as  $\text{FeCl}_3$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-865 Ferric chloride  $\text{FeCl}_3$
- 57.121 Ferric Choline Citrate Complex is the product resulting from the complexing of the soluble iron salt with choline dihydrogen citrate. Minimum iron (Fe) must be specified. When used as a commercial feed ingredient it must be declared as "ferric choline citrate". (Adopted 1977.)  
 IFN 6-20-867 Ferric choline citrate complex
- 57.127 Ferric Formate is an iron salt of formic acid generally expressed as  $\text{Fe}(\text{HCO}_2)_3$ . (Adopted 1980.)  
 IFN 6-630-089 Ferric formate  $\text{Fe}(\text{HCO}_2)_3 \cdot \text{H}_2\text{O}$
- 57.81 Ferric Phosphate is the iron salt of phosphoric acid generally expressed as  $\text{FePO}_4$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-859 Ferric phosphate  $\text{FePO}_4$
- 57.82 Ferric Pyrophosphate is the iron salt of pyrophosphoric acid generally expressed as  $\text{Fe}_2(\text{P}_2\text{O}_7)_3$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-861 Ferric pyrophosphate  $\text{Fe}_2(\text{P}_2\text{O}_7)_3$
- 57.129 Ferric Sulfate is the iron salt of sulfuric acid generally expressed as  $\text{Fe}_2(\text{SO}_4)_3$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1980.)  
 IFN 6-30-086 Ferric sulfate  $\text{Fe}_2(\text{SO}_4)_3$
- 57.77 Ferrous Carbonate is the iron salt of carbonic acid generally expressed as  $\text{FeCO}_3$ . Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-863 Ferrous carbonate  $\text{FeCO}_3$
- 57.128 Ferrous Chloride is the iron salt of hydrochloric acid generally expressed as  $\text{FeCl}_2$  and its hydrated forms. Minimum iron (Fe) must be specified. (Proposed 1979, Adopted 1981.)  
 IFN 6-30-090 Ferrous chloride  $\text{FeCl}_2$
- 57.75 Ferrous Fumarate is an iron salt of fumaric acid generally expressed as  $\text{FeC}_4\text{H}_2\text{O}_4$ . Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-08-097 Ferrous fumarate  $\text{FeC}_4\text{H}_2\text{O}_4$
- 57.79 Ferrous Gluconate is the iron salt of gluconic acid generally expressed as  $\text{Fe}(\text{C}_6\text{H}_{11}\text{O}_7)_2$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-01-867 Ferrous gluconate dihydrate  $\text{Fe}(\text{C}_6\text{H}_{11}\text{O}_7)_2 \cdot 2\text{H}_2\text{O}$
- 57.139 Ferrous Glycine Complex is the reaction product of one molecular equivalent of ferrous iron salt and two or more molecular equivalents of glycine, generally expressed as  $\text{FeC}_2\text{H}_3\text{N}_2\text{O}_4$ . Minimum iron (Fe) must be specified. When used as a commercial feed ingredient it must be declared as Ferrous Glycine. (Proposed 1984.)  
 IFN 6-17-227 Ferrous glycine complex  $\text{FeC}_2\text{H}_3\text{N}_2\text{O}_4$
- 57.83 Ferrous Sulfate is the iron salt of sulfuric acid generally expressed as  $\text{FeSO}_4$  and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975.)

IFN 6-01-869 Ferrous sulfate monohydrate  $\text{FeSO}_4 \cdot \text{H}_2\text{O}$ .  
 IFN 6-20-734 Ferrous sulfate heptahydrate  $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ .

57.30 Gypsiferrous Shale is a natural occurring shale type rock containing native calcium sulfate ( $\text{CaSO}_4$ ). It must carry guarantees of calcium (Ca) and sulfur (S). (Proposed 1977, Adopted 1981.)  
 IFN 6-14-505 Shale gypsiferrous

57.80 Iron Oxide is the oxide form of iron occurring both naturally and synthetically in various chemical valence compositions and colors -- sometimes expressed as  $\text{Fe}_2\text{O}_3$ . Minimum iron (Fe) must be specified. (Adopted 1975.)  
 IFN 6-02-431 Ferric oxide  $\text{Fe}_2\text{O}_3$

57.84 Iron, Reduced, is a metallic form of iron obtained by reducing ferric oxide with hydrogen. Minimum iron (Fe) must be specified. (Adopted 1975.)

IFN 6-02-429 Iron Reduced

57.9 Limestone, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Ground limestone must be used in all labeling. (Adopted 1952.)  
 IFN 6-02-632 Limestone ground

57.11 Limestone, Magnesium or Dolomite, is an acceptable source of magnesium and calcium carbonate. The terms are synonymous and designate a native mineral composed of mixtures of magnesium carbonate ( $\text{MgCO}_3$ ), and calcium carbonate ( $\text{CaCO}_3$ ). It must contain not less than 10% magnesium (Mg) and must be declared as an ingredient as magnesium limestone or dolomite limestone. (Adopted 1946, Amended 1952, 1965.)  
 IFN 6-02-633 Limestone dolomitic ground.  
 IFN 6-06-924 Limestone magnesium ground

57.85 Magnesium Carbonate is a magnesium salt of carbonic acid generally expressed as  $\text{MgCO}_3$ .  $\text{Mg}(\text{OH})_2$  and its hydrated forms. Minimum magnesium (Mg) must be specified. (Adopted 1975.)  
 IFN 6-02-754 Magnesium carbonate  $\text{MgCO}_3$ .  $\text{Mg}(\text{OH})_2$ .

IFN 6-08-797 Magnesium carbonate trihydrate  $\text{MgCO}_3 \cdot \text{Mg}(\text{OH})_2 \cdot 3\text{H}_2\text{O}$

IFN 6-29-798 Magnesium carbonate pentahydrate  $\text{MgCO}_3 \cdot \text{Mg}(\text{OH})_2 \cdot 5\text{H}_2\text{O}$

57.126 Magnesium Chloride is the magnesium salt of hydrochloric acid generally expressed as  $\text{MgCl}_2$  and its hydrated forms. Minimum magnesium (Mg) must be specified. (Proposed 1976, Adopted 1977.)  
 IFN 6-20-872 Magnesium chloride  $\text{MgCl}_2$

57.86 Magnesium Hydroxide is the hydrated form of magnesium generally expressed as  $\text{Mg}(\text{OH})_2$ . Minimum magnesium (Mg) must be specified. (Adopted 1975.)  
 IFN 6-26-012 Magnesium hydroxide  $\text{Mg}(\text{OH})_2$

57.140 Magnesium Phosphate is the magnesium salt of phosphoric acid, generally expressed as  $\text{MgHPO}_4$  and its hydrated forms. Minimum magnesium (Mg) and Phosphorus (P) and maximum fluorine (F) must be specified. It must contain not more than one part fluorine (F) to 100 parts phosphorus. (Proposed 1984.)  
 IFN 6-23-294 Magnesium phosphate  $\text{MgHPO}_4$

57.87 Magnesium Oxide is the oxide of magnesium generally expressed as  $\text{MgO}$ . Minimum magnesium (Mg) must be specified. (Adopted 1975.)  
 IFN 6-02-756 Magnesium oxide  $\text{MgO}$



57.24 Magnesium-Mica is a natural occurring magnesium, iron, and potassium layer silicate. It must be labeled with guarantees for magnesium (Mg), iron (Fe), and potassium (K). (Proposed 1968, Adopted 1971, Amended 1987)  
IFN 6-08-999 Magnesium-Mica

57.88 Magnesium Sulfate is the magnesium salt of sulfuric acid generally expressed as  $MgSO_4$  and its hydrated forms. Minimum magnesium (Mg) must be specified. (Adopted 1975.)

IFN 6-26-134 Magnesium sulfate  $MgSO_4$

IFN 6-12-209 Magnesium sulfate monohydrate  $MgSO_4 \cdot H_2O$

IFN 6-02-758 Magnesium sulfate heptahydrate  $MgSO_4 \cdot 7H_2O$

57.89 Manganese Acetate is the manganese salt of acetic acid generally expressed as  $Mn(C_2H_3O_2)_2$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-034 Manganese acetate tetrahydrate  $Mn(C_2H_3O_2)_2 \cdot 4H_2O$

57.90 Manganese Carbonate is the manganese salt of carbonic acid generally expressed as  $MnCO_3$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-036 Manganese carbonate  $MnCO_3$

57.91 Manganese Chloride is the manganese salt of hydrochloric acid generally expressed as  $MnCl_2$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-038 Manganese chloride tetrahydrate  $MnCl_2 \cdot 4H_2O$

57.92 Manganese Citrate (Soluble) is the manganese salt of citric acid generally expressed as  $Mn_3(C_6H_5O_7)_2$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-040 Manganese citrate soluble  $Mn_3(C_6H_5O_7)_2$

57.93 Manganese Gluconate is the manganese salt of gluconic acid generally expressed as  $Mn(C_6H_{11}O_7)_2$ . Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-044 Manganese gluconate  $Mn(C_6H_{11}O_7)_2$

57.94 Manganese Orthophosphate is the manganese salt of phosphoric acid generally expressed as  $Mn_3(PO_4)_2$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-047 Manganese orthophosphate trihydrate  $Mn_3(PO_4)_2 \cdot 3H_2O$

57.95 Manganese Phosphate (dibasic) is the manganese salt of phosphoric acid generally expressed as  $MnHPO_4$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-048 Manganese phosphate dibasic  $MnHPO_4$

57.96 Manganese Sulfate is the manganese salt of sulfuric acid generally expressed as  $MnSO_4$  and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-050 Manganese sulfate tetrahydrate  $MnSO_4 \cdot 4H_2O$

57.97 Manganese Oxide is an oxide form of manganese generally expressed as  $MnO$ . Minimum manganese (Mn) must be specified. (Adopted 1975.)

IFN 6-03-054 Manganese oxide  $MnO$

57.150 Metal Amino Acid Complex is the product resulting from complexing of a soluble metal salt (such as potassium or manganese) with an amino acid(s). Minimum metal content must be declared. When used as a commercial feed ingredient, it must be declared as a specific metal amino acid complex, i.e., potassium amino acid complex; copper, amino acid complex; zinc, amino acid complex; magnesium, amino acid complex; iron, amino acid complex; cobalt,

amino acid complex; calcium, amino acid complex; and manganese, amino acid complex. (Adopted 1990)

IFN 6-32-053 Copper, amino acid complex

IFN 6-32-054 Zinc, amino acid complex

IFN 6-32-055 Magnesium, amino acid complex

IFN 6-32-056 Iron, amino acid complex

IFN 6-32-057 Cobalt, amino acid complex

IFN 6-32-058 Calcium, amino acid complex

IFN 6-32-059 Potassium, amino acid complex

IFN 6-32-060 Manganese, amino acid complex

57.151 Metal (specific amino acid) Complex is the product resulting from complexing a soluble metal salt with a specific amino acid. Minimum metal content must be declared. When used as a commercial feed ingredient, it must be declared as a specific metal, specific amino acid, i.e., copper lysine complex, zinc lysine complex, ferric methionine complex, manganese methionine complex and zinc methionine complex (Proposed 1991, Adopted 1992)

IFN Copper lysine complex

IFN Zinc lysine complex

IFN 6-16-294 Ferric methionine complex

IFN 6-19-212 Manganese methionine complex

IFN 6-16-293 Zinc methionine complex

57.142 Metal Amino Acid Chelate is the product resulting from the reaction of a metal ion from a soluble metal salt with amino acids with a mole ratio of one mole of metal to one to three (preferably two) moles of amino acids to form coordinate covalent bonds. The average weight of the hydrolyzed amino acids must be approximately 150 and the resulting molecular weight of the chelate must not exceed 800. The minimum metal content must be declared. When used as a commercial feed ingredient it must be declared as a specific metal amino acid chelate; i.e., Calcium Amino Acid Chelate, Cobalt Amino Acid Chelate, Copper Amino Acid Chelate, Iron Amino Acid Chelate, Magnesium Amino Acid Chelate, Manganese Amino Acid Chelate or Zinc Amino Acid Chelate. (Proposed 1986, Adopted 1988)

IFN 6-20-981 Calcium amino acid chelate

IFN 6-20-982 Cobalt amino acid chelate

IFN 6-20-983 Copper amino acid chelate

IFN 6-20-984 Iron amino acid chelate

IFN 6-20-985 Magnesium amino acid chelate

IFN 6-20-986 Manganese amino acid chelate

IFN 6-20-987 Zinc amino acid chelate

57.29 Metal Polysaccharide Complex is the product resulting from complexing of a soluble salt with a polysaccharide solution declared as an ingredient as the specific metal complex i.e., copper polysaccharide complex, zinc polysaccharide complex, iron polysaccharide complex, cobalt polysaccharide complex and manganese polysaccharide complex (Proposed 1971, Adopted 1973.)

IFN 8-09-822, Copper polysaccharide complex

IFN 8-09-898 Iron polysaccharide complex

IFN 8-09-899 Zinc polysaccharide complex

IFN 8-19-206 Magnesium polysaccharide complex

57.23 Metal Proteinate is the product resulting from the chelation of a soluble salt with amino acids and/or partially hydrolyzed protein. It must be declared as an ingredient as the specific metal proteinate; i.e. Copper Proteinate,

Zinc Proteinate, Magnesium Proteinate, Iron Proteinate, Cobalt Protein, Manganese Protein, or Calcium Protein. (Proposed 1967, Adopted 1970, Amended 1977, Amended 1987.)

IFN 6-09-896 Copper protein.

IFN 6-09-897 Zinc protein.

IFN 6-26-149 Magnesium protein.

IFN 6-26-150 Iron protein.

IFN 6-26-151 Cobalt protein.

IFN 6-16-834 Manganese protein.

IFN 6-16-833 Calcium protein.

57.4 Oyster Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952.)

IFN 6-03-481 Oyster shells fine ground (Oyster shell flour).

57.22 Ammonium Polyphosphate Solution is the product resulting from the neutralization of superphosphoric acid. It must contain not less than 9% nitrogen (N) and 13% phosphorus (P). It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As), and 30 ppm of heavy metals reported as lead.

It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than 2% of equivalent crude protein in the total daily ration.

It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from this source shall not exceed 1.25% of the total daily ration.

When incorporated into a feed for non-ruminants the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows:

(example) BLUE BIRD HOG FINISHER

Crude Protein (Minimum).....16%  
(This includes not more than \_\_\_\_\_ %  
equivalent crude protein which is not  
nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 2% equivalent crude protein from ammonium polyphosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% equivalent crude protein from equivalent crude protein from ammonium polyphosphate, then the label must contain adequate directions for use, and a prominent statement: "Warning -- This feed must be used only in accordance with directions furnished on the label." (Proposed 1966, Adopted 1967, Amended 1981.)

IFN 6-08-42 Ammonium polyphosphate solution

57.134 Calcium Phosphate is a calcium phosphate product either calcined, fused, precipitated or reacted. It must contain not more than one part fluorine (F) to 100 parts of phosphorus (P). The minimum percent of calcium (Ca) and phosphorus (P) and maximum percent of fluorine (F) must be stated on the label. (Proposed 1980, Adopted 1981.)

IFN 6-12-311 Calcium phosphate

57.16 Diammonium Phosphate is the product resulting from neutralization of phosphoric acid, feed grade, or defluorinated wet-process phosphoric acid which contains not less than 17% nitrogen (N) and 20% phosphorus (P). It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As), and 30 ppm of heavy metals reported as lead. This

does not include diammonium phosphate made from by-product ammonia absorbed from coke-oven gas.

It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than 2% of equivalent crude protein in the total daily ration.

It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from diammonium phosphate must be guaranteed and the equivalent crude protein from this source shall not exceed 1.25% of the total daily ration.

When incorporated into a feed for non-ruminants, the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows:

(example)

BLUE BIRD HOG FINISHER

Crude protein (minimum).....16%  
(This includes not more than \_\_\_\_\_ %  
equivalent crude protein which is not  
nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 2% equivalent crude protein from diammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% equivalent crude protein from diammonium phosphate, then the label must contain adequate directions for use, and a prominent statement: "Warning -- This feed must be used only in accordance with directions furnished on the label." (Proposed 1961, Amended 1967, 1981.)

IFN 6-00-370 Ammonium phosphate dibasic (NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub>

57.71 Dicalcium Phosphate is a calcium salt of phosphoric acid generally expressed as CaHPO<sub>4</sub> and its hydrated forms. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must not contain more than 1 part of fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-01-080 Calcium phosphate dibasic from defluorinated phosphoric acid. IFN 6-26-335 Calcium phosphate dibasic from furnace phosphoric acid (Dicalcium phosphate).

57.33 Disodium Phosphate is a sodium salt of phosphoric acid generally expressed as Na<sub>2</sub>HPO<sub>4</sub> and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must not contain more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-04-286 Sodium phosphate dibasic Na<sub>2</sub>HPO<sub>4</sub>

57.33 Mono ammonium phosphate is the product resulting from the neutralization of phosphoric acid, feed grade, or defluorinated wet-process phosphoric acid which contains not less than 9% nitrogen (N) and 23% phosphorus (P). It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As) and 30 ppm of heavy metals reported as lead (Pb). It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than 2% of equivalent crude protein in the total daily ration.

It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from mono-ammonium phosphate must be guaranteed and the equivalent crude protein from this source shall not exceed 1.25% of the total daily ration.

When incorporated into a feed for non-ruminants the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows:

(example)  
 BLUE BIRD HOG FINISHER  
 Crude Protein (Minimum).....16%  
 (This includes not more than \_\_\_\_\_%  
 equivalent crude protein which is not  
 nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 3% equivalent crude protein from mono-ammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% equivalent crude protein from mono-ammonium phosphate, then the label must contain adequate directions for use, and a prominent statement: "Warning--This feed must be used only in accordance with directions furnished on the label." (Proposed 1973, Adopted 1976, Reg. 582.1141)

IFN 6-09-338 Ammonium phosphate monobasic  $(\text{NH}_4\text{H}_2\text{PO}_4)$

57.98 Monocalcium Phosphate is a calcium salt of phosphoric acid generally expressed as  $\text{CaH}_4(\text{PO}_4)_2$  and its hydrated forms. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-01-082 Calcium phosphate, monobasic, from defluorinated phosphoric acid.

IFN 6-26-334 Calcium phosphate, monobasic, from furnace phosphoric acid (monocalcium phosphate).

57.99 Monosodium Phosphate is a sodium salt of phosphoric acid generally expressed as  $\text{NaH}_2\text{PO}_4$  and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-04-288 Sodium phosphate monobasic monohydrate  $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$

57.19 Phosphoric Acid, \_\_\_\_\_%, is a solution of phosphoric acid in water generally expressed as  $\text{H}_3\text{PO}_4$ . Minimum phosphorus (P) must be specified. It must not contain more than 100 parts per million fluorine (F) and 3.2 parts per million Arsenic (As) for each percentage of phosphorus present. When this ingredient is used as a constituent in mixed feeds, it must be indicated in the ingredient list as "phosphoric acid." (Proposed 1957, Adopted 1962, Amended 1967, 1968, 1975, 1976.)

IFN 6-03-707 Phosphoric acid  $\text{H}_3\text{PO}_4$

57.12 Phosphate, Defluorinated, includes either calcined, fused, precipitated or reacted calcium phosphate. It must contain not more than one part of fluorine (F) to 100 parts of phosphorus (P). The minimum percent of calcium (Ca) and phosphorus (P) and the maximum percent of fluorine (F) must be stated on the label. The term "defluorinated" must not be used as a part of the name of any product containing more than one part of fluorine (F) to 100 parts of phosphorus (P). The term "defluorinated phosphate" must be used, where appropriate, in labeling ingredient listings. (Adopted 1952, Amended 1965.)

IFN 6-01-780 Phosphate defluorinated.

IFN 6-12-330 Phosphate defluorinated 18.5% phosphorus.

IFN 6-12-324 Phosphate defluorinated 18% phosphorus.

IFN 6-12-331 Phosphate defluorinated 21% phosphorus.

57.15 Rock Phosphate, Soft, is the very finely divided by-product (washings) obtained from mining Florida rock phosphate by the hydraulic process. It must contain a minimum of 9% phosphorus (P) and 15% calcium (Ca), and not more than 30% clay and 1.5% fluorine (F). The term soft rock phosphate must be used in all labeling. (Proposed 1961, Adopted 1963, Amended 1965.)

IFN 6-03-947 Rock phosphate soft

57.20 Rock Phosphate, Ground, is ground phosphate rock. It must be labeled with guarantees for calcium (Ca) and phosphorus (P) and a maximum guarantee for fluorine (F). Ground rock phosphate must be used in all labels. (Proposed 1963, Adopted 1964.)

IFN 6-03-945 Rock phosphate ground

57.21 Rock Phosphate, Ground, Low Fluorine is ground phosphate rock that contains not more than 0.5% fluorine (F). Low fluorine ground rock phosphate must be used in all labeling. It must be labeled with guarantees for minimum percentages of calcium (Ca) and phosphorus (P) and for a maximum percentage of fluorine (F). (Proposed 1963, Adopted 1964.)

IFN 6-03-946 Rock phosphate ground low fluorine

57.132 Sodium Hexametaphosphate is the sodium salt of Phosphoric Acid generally expressed as  $(\text{NaPO}_3)_x \cdot \text{H}_2\text{O}$  ( $x = 6-20$ ). Minimum sodium and maximum fluorine must be specified. It must not contain more than one part fluorine (F) to 100 parts phosphorus (P), 75 parts per million of arsenic (As) and 30 parts per million of heavy metals reported as lead. (Proposed 1980, Adopted 1981.)

IFN 6-12-315 Sodium hexametaphosphate  $(\text{NaPO}_3)_x \cdot \text{H}_2\text{O}$  ( $x = 6-20$ )

57.110 Sodium Tripolyphosphate, is a sodium salt of phosphoric acid generally expressed as  $\text{Na}_5\text{P}_3\text{O}_{10}$ . Minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-08-076, Sodium tripolyphosphate  $\text{Na}_5\text{P}_3\text{O}_{10}$

57.125 Tribasic Sodium Phosphate is the sodium salt of phosphoric acid generally expressed as  $\text{Na}_3\text{PO}_4$  and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than 1 part fluorine (F) to 100 parts of phosphorus (P). (Proposed 1976, Adopted 1977.)

IFN 6-20-871 Sodium phosphate tribasic  $\text{Na}_3\text{PO}_4$

57.113 Tricalcium Phosphate is a calcium salt of phosphoric acid generally expressed as  $\text{Ca}_3(\text{PO}_4)_2$ . Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975.)

IFN 6-01-084 Calcium phosphate tribasic

57.100 Potassium Bicarbonate is a potassium salt of carbonic acid generally expressed as  $\text{KHCO}_3$ . Minimum potassium (K) must be specified. (Adopted 1975.)

IFN 6-09-337 Potassium bicarbonate  $\text{KHCO}_3$

57.101 Potassium Carbonate is a potassium salt of carbonic acid generally expressed as  $\text{K}_2\text{CO}_3$ . Minimum potassium (K) must be specified. (Adopted 1975.)

IFN 6-09-336 Potassium carbonate  $\text{K}_2\text{CO}_3$

57.130 Potassium Citrate is a potassium salt of citric acid generally expressed as  $\text{K}_3\text{C}_6\text{H}_5\text{O}_7 \cdot \text{H}_2\text{O}$  and its hydrated forms. Minimum potassium (K) must be specified. (Adopted 1980.)

IFN 6-30-087 Potassium citrate  $\text{K}_3\text{C}_6\text{H}_5\text{O}_7 \cdot \text{H}_2\text{O}$

57.102 Potassium Chloride, is the potassium salt of hydrochloric acid generally expressed as KCl. Minimum potassium (K) must be specified. (Adopted 1975.)

IFN 6-03-755 Potassium chloride KCl

57.124 Potassium Hydroxide is the hydroxyl form of potassium generally expressed as KOH. Minimum potassium (K) must be specified. (Proposed 1976, Adopted; 1977.) Reg. 582-1631. IFN 6-20-870 Potassium hydroxide KOH

57.103 Potassium Iodate is the potassium salt of iodic acid generally expressed as  $KIO_3$ . Minimum potassium (K) and minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-08-072 Potassium iodate  $KIO_3$

57.104 Potassium Iodide is the potassium salt of hydriodic acid generally expressed as KI. Minimum potassium (K) and iodine (I) must be specified. (Adopted 1975.)

IFN 6-03-759 Potassium iodide KI

57.105 Potassium Sulfate is the potassium salt of sulfuric acid generally expressed as  $K_2SO_4$ . Minimum potassium (K) and sulfur (S) must be specified. (Adopted 1975.)

IFN 6-08-098 Potassium sulfate  $K_2SO_4$

57.31 Salt is an acceptable source of sodium chloride. It must be true to name and contain not less than 95% sodium chloride. (Proposed 1973, Adopted 1975.)

IFN 6-04-152 Salt NaCl

57.13 Iodized Salt, is a common salt (NaCl) containing not less than 0.007% iodine, uniformly distributed. (Adopted 1942.)

IFN 6-04-151 Salt iodine added 0.007% iodine

57.5 Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952.)

IFN 6-05-688 Multis shells fine ground

57.137 Sodium Acid Pyrophosphate is the disodium salt of pyrophosphoric acid, generally expressed as  $Na_2H_2P_2O_7 \cdot 6H_2O$  and other hydrated forms. Minimum phosphorus (P), minimum sodium (Na), and maximum fluorine (F), must be specified. It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1984.)

IFN 6-16-830 Sodium, Pyrophosphate, Hexahydrate

57.106 Sodium Bicarbonate is the sodium salt of carbonic acid generally expressed as  $NaHCO_3$ . Minimum sodium (Na) must be specified. (Proposed 1988, Adopted 1989)

IFN 6-04-272 Sodium bicarbonate  $NaHCO_3$

57.133 Sodium Carbonate is the sodium salt of carbonic acid generally expressed as  $Na_2CO_3$  and its hydrated forms. Minimum sodium (Na) must be specified. (Proposed 1980, Adopted 1981.)

IFN 6-12-316 Sodium carbonate  $Na_2CO_3$

57.107 Sodium Iodate is the sodium salt of iodic acid generally expressed as  $NaIO_3$ . Minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-04-277 Sodium iodate  $NaIO_3$

57.108 Sodium Iodide is the sodium salt of hydriodic acid generally expressed as NaI. Minimum sodium (Na) and minimum iodine (I) must be specified. (Adopted 1975.)

IFN 6-04-279 Sodium iodide NaI.

57.145 Sodium Molybdate is the sodium salt of molybdenum, generally expressed as  $Na_2MoO_4$ , and its hydrated forms. Minimum molybdenum must be specified (Proposed 1987, Adopted 1988.)

IFN 6-19-30 Sodium molybdate

57.120 Sodium Selenate is a sodium salt of selenic acid generally expressed as  $Na_2SeO_4$  and its hydrated forms. Minimum selenium (Se) must be specified. All premises shall bear adequate directions and cautions for use including this statement "Caution. Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted." (Adopted 1975.) Reg. 573.920

IFN 6-26-014 Sodium selenate  $Na_2SeO_4$

57.119 Sodium Selenite is a sodium salt of selenious acid generally expressed as  $Na_2SeO_3$  and its hydrated forms. Minimum selenium (Se) must be specified. All premises shall bear adequate directions and cautions for use including this statement "Caution. Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted." (Adopted 1975.) Reg. 573.920 IFN 6-26-013 Sodium selenite  $Na_2SeO_3$

57.138 Sodium Sesquicarbonate is the mixed sodium salt of carbonic acid, generally expressed as  $Na_2CO_3 \cdot NaHCO_3 \cdot 2H_2O$ , providing not less than 90% of the hydrated double salt with 42% minimum sodium carbonate, 33% minimum sodium bicarbonate, and providing not less than 27.5% sodium. (Proposed 1988, Adopted 1989.)

IFN 6-17-895 Sodium sesquicarbonate

57.109 Sodium Sulfate is the sodium salt of sulfuric acid generally expressed as  $Na_2SO_4$  and its hydrated forms. The minimum sodium (Na) and minimum sulfur (S) must be specified. (Adopted 1975.)

IFN 6-04-291, Sodium sulfate decahydrate  $Na_2SO_4 \cdot 10H_2O$

57.111 Sulfur is elemental sulfur generally expressed as sulfur (S). Minimum sulfur (S) must be specified. (Adopted 1975.)

IFN 6-04-705 Sulfur

57.112 Thymol Iodide is a mixture of iodine derivatives of thymol generally expressed as  $C_{10}H_{14}I_2O_2$ . Minimum iodine (I) must be specified. (Adopted 1975.) IFN 6-04-857 Thymol iodide  $C_{10}H_{14}I_2O_2$

57.114 Zinc Acetate, is the zinc salt of acetic acid generally expressed as  $Zn(C_2H_3O_2)_2$  and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975.)

IFN 6-05-547, Zinc acetate dihydrate  $Zn(C_2H_3O_2)_2 \cdot 2H_2O$

57.115 Zinc Carbonate is the zinc salt of carbonic acid generally expressed as  $ZnCO_3$  and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975.) IFN 6-05-549 Zinc carbonate  $ZnCO_3$

57.116 Zinc Chloride is the zinc salt of hydrochloric acid generally expressed as  $ZnCl_2$  and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975.)

IFN 6-05-551 Zinc chloride  $ZnCl_2$

57.143 Zinc Chloride Diamine Complex is the product resulting from the complexing of zinc with ammonium chloride and is generally expressed as  $[Zn(NH_3)_2]Cl_2$ . Minimum zinc (Zn) must be specified. (Proposed 1986, Adopted 1987.)

IFN 6-20-988 Zinc chloride diamine complex

57.117 Zinc Oxide is the oxide form of zinc generally expressed as ZnO. Minimum zinc (Zn) must be specified. (Adopted 1975.)

## IFN 6-05-553 Zinc oxide ZnO

57.118 Zinc Sulfate is the zinc salt of sulfuric acid generally expressed as  $\text{ZnSO}_4$  and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975.)

IFN 6-05-555 Zinc sulfate monohydrate  $\text{ZnSO}_4 \cdot \text{H}_2\text{O}$ IFN 6-20-729 Zinc sulfate heptahydrate  $\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$ 

## Tentative

57.152 Calcium Formate is the calcium salt of formic acid generally expressed as  $\text{Ca}(\text{HOCO})_2$  and its hydrated forms. It is to be used as a source of supplemental calcium in swine diets, not to supply more than 0.6% calcium to the diet. Calcium Formate is currently considered an unapproved food additive, and a food additive petition must be approved prior to its use in feeds. (Adopted 1993, Amended 1999)

57.153 Copper Acetate Monohydrate is the copper salt of acetic acid generally expressed as  $\text{Cu}(\text{C}_2\text{H}_3\text{O}_2)_2 \cdot \text{H}_2\text{O}$  and its hydrated forms. Minimum copper must be specified. (Proposed 1993)

57.158 Copper Citrate is the copper salt of citric acid generally expressed as  $\text{C}_6\text{H}_4\text{Cu}_2\text{O}_7$ . It is to be used as a source of copper in broiler feeds at levels not exceeding 185 ppm of total dietary copper. Minimum copper (Cu) must be specified. (Proposed 1997)

57.155 Chromium Tripicolinate. Chromium tripicolinate is the product resulting from reaction of chromium chloride with picolinic acid. It is to be used as a source of supplemental chromium in swine diets, not to supply more than 200 ppb of chromium to the diet. Minimum chromium from chromium tripicolinate must be specified. (Proposed 1996)

57.160 Metal Propionate is the product resulting from reaction of a metal salt with propionic acid. The metal propionates are prepared with an excess of propionic acid, at an appropriate stoichiometric ratio. It must be declared as an ingredient of the specific metal propionate, i.e. zinc propionate. Minimum metal content must be declared. (Proposed 1999)

## Descriptions of Salts, Complexes and Chelates

**Metal (Mineral) Salt** - an ionic substance containing a metal cation and either an inorganic or an organic anion. The water soluble portion of a Metal (Mineral) Salt dissociates in water to give the hydrated metal cation and the free anion (or its hydrolysis product) in solution.

**Metal (Mineral) Complex** - a substance in which a metal cation (electron pair acceptor) accepts and electron pair from one or more anionic or neutral bonding partners (ligands, electron pair donors) to form chemical bonds. The water soluble portion of the complex remains as the intact complex in aqueous solution.

**Metal (Mineral) Chelate** - a metal complex (see preceding term) in which at least one ligand (electron pair donor) forms two or more bonds to the central metal ion through different atoms of the ligand. A distinctive feature of a metal chelate in the presence of a heterocyclic ring(s) in which the metal is a member of the ring. In the water soluble portion of the chelate, the heterocyclic ring(s) remains intact.

## Official Guidelines for

Contaminant Levels Permitted in Mineral Feed Ingredients  
Investigator and Section Editor—Jim Balthrop, TX

The Committee considered the matter of contaminants in mineral feed ingredients for several years before adopting an approach to the problem as reported in the 1978 Official Publication. The selected approach was combined with the 1980 National Academy of Sciences "Mineral Tolerances of Domestic Animals" toxicity data to produce these guidelines.

The mineral section of the 1982 AAFCO Official Publication contains 114 mineral ingredient definitions for sources of 12 elements plus salt to consider in drafting guidelines to limit contaminants. Some of the variables, among others, used in guideline development are:

- (1) Differing nutrient requirements between species and also within species, e.g., young vs. mature, lactating vs. nonlactating, and layers vs. broilers.
- (2) Similarly, the toxicity of a contaminant varies between and within species.
- (3) The concentration of a nutrient varies between several ingredient sources, e.g., magnesium oxide ( $\text{MgO}$ ) contains 6 times the magnesium (Mg) contained in magnesium sulfate heptahydrate ( $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ ) and thus could contain 6 times the contaminant level since only one-sixth as much would be needed to meet the nutrient requirement.
- (4) The range between a nutrient requirement and toxicity for a given element varies greatly. Selenium, for example, is required at approximately 0.1 ppm but should not be fed above 2 ppm. Manganese, on the other hand, is required at about 50 ppm but levels as high as 1,000-2,000 ppm can be tolerated.
- (5) Knowledge of nutrient requirements and toxicities is incomplete and/or imprecise in many cases.

If the variables are acknowledged it becomes apparent that precise contaminant limits, fixed at the very brink of toxicity, are impractical. Rather, we must work in much more general terms, using scientific data to the limit possible but not excluding some subjective decisions based upon common sense. Safety factors, for example, would be included in the latter category.

With the above factors in mind, the following approach was used in developing the overall schedule for handling contaminants in mineral feed ingredients proposed in this report.

- (1) Determine the all-species average requirement for each of the 12 elements and salt included in the AAFCO mineral definitions. These values (Table 1) were adapted from the National Academy of Science-Nutrition Research Council recommendations.
- (2) Determine the all-sources average content for each element.
- (3) Calculate, from the data in 1 and 2 above, the dilution factor needed to meet NRC recommended levels for each element (Table 3). Example: If the average calcium content from all AAFCO sources is 25% and the NRC recommendation is 1%, the dilution factor is 25. In other words, the calcium source will be diluted by a factor of 25 on total ration basis.
- (4) Determine a safety factor, 2.5 is used in this report.
- (5) Group contaminants according to toxicity following the general guidelines proposed in the 1978 report of this committee. Four groups are recommended: Highly Toxic, Toxic, Moderately Toxic, and Slightly Toxic (Table 2).
- (6) Set limits within each group as follows:
  - (a) Contaminant levels below which no declaration or labeling for the contaminant is required or deemed appropriate.

- (b) A range of contaminant levels permitted in feed ingredients if, but only if, the product is labeled as to the contaminant level. "Labeling" here and elsewhere is considered in the broader sense, i.e., "Typical Analysis Specification Sheet" or similar information supplied by the manufacturer to customers.
- (c) Contaminant levels above which the product's use as a feed ingredient is prohibited.

(7) Select a dilution factor (see item 3 above) to be used in setting the maximum contaminant level permitted in a feed ingredient without labeling the amount present. A dilution factor of 25 is recommended and was used in arriving at the values in Table 2. This is the lowest value in Table 3 (for calcium) and thus provides the greatest margin of safety.

(8) Calculate maximum level permitted in ingredients, without labeling, for each of the 4 groups, using the following equation:

$$MLP = \frac{CEL \times DF}{SF}$$

where--

MLP = Maximum level permitted without labeling (on "Typical Composition Specification Sheets" for example)

CEL = NAS recommended maximum continuous feeding level for the most toxic element in the group

DF = Dilution Factor

SF = Safety Factor

Example:

In the Highly Toxic group (Table 2) of cadmium, mercury and selenium, cadmium has the lowest continuous feeding level at 0.5 ppm. Therefore, if  $DF = 25$  and  $SF = 2.5$ ,  $MLP = \frac{0.5 \text{ ppm} \times 25}{2.5} = 5 \text{ ppm}$ . Thus, ingredients

containing 5 ppm or less of the Highly Toxic group contaminants will not raise the level in the total ration above the continuous feeding level maximum for any of them.

The MLP values for the other 3 groups were determined similarly.

(9) Determine range of contaminant levels permitted, by group, if levels are stated in the labeling. This is a judgment decision.

(10) Determine contaminant levels, by group, above which an ingredient would be excluded from use in a feed. This is also a judgment decision.

The procedure recommended above provides a systematic approach to establishing contaminant limits in feed ingredients based upon toxicity data in "Mineral Tolerance of Domestic Animals." The equation used to set the limits is designed to handle worst case situations, since it is based upon the most toxic element in each group and assumes the lowest dilution of the ingredient (dilution factor of 25). Thus, an additional margin of safety is provided automatically for all but the highest toxicity contaminants in each group and for the highest nutrient requirements.

Flourine is not included in Table 2. It is closely associated with phosphate ingredients and has been handled successfully for many years by requiring the phosphorus: fluorine ratio to be not less than 100:1. It is recommended this policy continue unchanged.

Table 1. Approximate Trace Mineral Requirements (total diet basis)<sup>1</sup>

	Calcium	Phosphorus	Potassium	Salt	Sulfur	Cobalt	Copper	Iron	Iodine	Magnesium	Manganese	Selenium <sup>2</sup>	Zinc
Swine	0.6	0.4	0.3	0.2	--	0.1	10	80	0.04	400	40	0.1	50
Dairy	0.5	0.4	0.7	0.25	0.2	0.1	10	100	0.10	600	20	0.1	40
Beef	0.4	0.3	--	0.5	--	0.1	6	--	--	500	55	0.1	--
Poultry	3.0	0.7	0.4	0.2	--	--	4	80	0.35	600	--	0.1	50
Sheep	0.4	0.3	--	0.5	0.1	0.07	5	--	0.39	600	--	0.1	100
All-Species	1.0	0.4	0.5	0.4	0.2	0.1	7	90	0.20	600	30	0.1	60
Average	0.4	0.4	0.5	0.4	0.2	0.1	7	90	0.20	600	30	0.1	60

<sup>1</sup>Adapted from NAS-NRC recommendations. The purpose of this Table is to estimate dilution factors for heavy metals present in minerals used for animal nutrition in feeds.

<sup>2</sup>FDA approved levels.

Table 2. Official Guidelines Suggested for Contaminants in Individual Mineral Feed Ingredients\*

Category	Maximum Tol. Lev. in Complete Feed (PPM) <sup>(1)</sup>	Typical Analysis Not Sug. Below Label (PPM)	Typical Analysis Suggested Between (PPM)	Prohibited Above (PPM)
<b>1. HIGHLY TOXIC</b>				
Cadmium	1-9	5	5-500	500
Mercury	0.5			
Selenium	2			
<b>2. TOXIC</b>				
Cobalt	10-40	100	100-1000	1000
Molybdenum	10 <sup>(4)</sup>			
Vanadium	10			
Barium	20			
Tungsten	20			
Copper	25 <sup>(3)</sup>			
Lead	30			
<b>3. MODERATELY TOXIC</b>				
Arsenic	41-100	500	500-2000	2000
Nickel	50			
Iodine	50			
Antimony	70			
<b>4. SLIGHTLY TOXIC</b>				
Boron	101-1000	2000	> 2000	None
Aluminum	150			
Bromine	200 <sup>(2)</sup>			
Zinc	200			
Bismuth	300			
Manganese	400			
Chromium	400			
	1000			

(1) Dietary Level that, for a limited period, will not impair animal performance and should not produce unsafe residues in human food derived from that animal. Values cited are those for the most sensitive animal species in "Mineral Tolerance of Domestic Animals," National Academy of Sciences/National Research Council, Washington, D.C. (1980).

(2) NAS/NRC publication reference above; as soluble salts of high bioavailability. Higher levels of less-soluble forms found in natural substances can be tolerated. Species for this level is poultry; swine, horse, and rabbit are estimated to be similar by interspecific extrapolation; cattle & sheep 1,000 ppm.

(3) Some animal species such as sheep may be particularly sensitive to high levels of copper.

(4) It is generally recognized that molybdenum may be included in sheep feed at 1-3 ppm as an added nutrient.

Table 3. Approximate Dilution Factors and Typical Contaminant Levels of AAFCO Defined Mineral Feed Ingredients

Contaminant	Recommended level (ppm)	Approx. dil. to meet level	Typical Contaminant Levels (PPM)
Calcium	1.0	10	Antimony
Phosphorus	0.4	2.5 x 10 <sup>1</sup>	Nickel
Potassium	0.5	9 x 10 <sup>1</sup>	Cadmium
Salt	0.4	2.5 x 10 <sup>2</sup>	Mercury
Sulfur	0.2	7 x 10 <sup>1</sup>	Lead
Cobalt	0.1	3 x 10 <sup>6</sup>	Arsenic
Copper	7	7 x 10 <sup>4</sup>	
Iron	90	3 x 10 <sup>5</sup>	
Iodine	0.2	4 x 10 <sup>6</sup>	
Manganese	30	1.2 x 10 <sup>4</sup>	
Magnesium	600	3 x 10 <sup>2</sup>	
Selenium	0.1	4 x 10 <sup>6</sup>	
Zinc	60	8 x 10 <sup>2</sup>	

\*Adapted from "NFA Mineral Ingredients Handbook," National Feed Ingredients Association, 1979 edition, and from "AFLA Feed Ingredient Guide," American Feed Industry Association, Inc.

## 60. MISCELLANEOUS PRODUCTS

Investigator and Section Editor--Shannon Jordre, SD

\*Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: "Do not feed to cattle or other ruminants".

## Official

60.1 Dried Apple Pomace is the sound, dried residue obtained by the removal of cider from apples. (Adopted 1929.)

IFN 4-00-423 Apple pomace dehydrated

60.2 Dried Apple Pectin Pulp is the sound, dried residue obtained by the removal of pectin from apple products. (Adopted 1929.)

IFN 4-00-425 Apple pomace without pectin dehydrated

60.7 Almond Hulls--are obtained by drying the pericarp which surrounds the nut. Almond hulls shall contain not more than 13 percent moisture, 15 percent crude fiber and 9 percent ash. Total soluble sugars expressed as invert shall not be less than 18 percent. Almond hulls shall be processed in accordance with good manufacturing practices and be reasonably free of foreign material. (Proposed 1984, Adopted 1985.)

IFN 4-00-358 Almond hulls ground

60.72 Almond Hulls with Almond Shells--Almond hulls with almond shells must not contain more than 29 percent crude fiber, 9 percent ash and 13 percent moisture. They shall be processed in accordance with good manufacturing practices and be reasonably free of foreign material. (Proposed 1984, Adopted 1985.)

IFN 1-27-475 Almond hulls with shells

60.42 Ground Almond Shells is obtained by drying and grinding that portion of the almond fruit which surrounds the nut. It must be reasonably free of the nut shell and other foreign material. (Adopted 1953)

IFN 4-00-358 Almond hulls ground

60.44 Ground Whole Aspen and/or Parts is generally recognized as a feed ingredient in cattle diets when used in accordance with good nutritional practices. Ground whole aspen (*Populus tremuloides* Michx. and *Populus grandidentata*) is composed of the entire tree including leaves, branches, trunk, and bark. Ground aspen parts may also include leaves, branches, trunk, and bark. Roots and stumps are excluded to avoid contamination of dirt and rocks in the product. The particle size of the product shall not exceed 3/8 inches. (Proposed 1979, Adopted 1980.)

IFN 1-30-183 Aspen quaking/Aspen large toothed aerial part ground

IFN 1-12-241 Aspen aerial part ground

60.43 Aspirated Grain Fractions--are obtained during the normal aspiration of cereal grains and/or oil seeds for the purpose of environmental control and safety within a grain handling facility. It shall consist primarily of seed parts and may not contain more than 15% ash. It shall not contain aspirations from medicated feeds. (Proposed 1979, Amended 1980, Adopted 1980.)

IFN 4-12-208 Cereals-oil seeds grain and seed fractions aspirated

60.26 Bagasse is that portion of the stalk of sugar cane, after removal of leaves and tops, remaining after extraction of the juice. (Proposed 1971, Adopted 1972.)

IFN 1-04-686 Sugarcane bagasse dehydrated

60.15 Dried Bakery Product is a mixture of bread, cookies, cake, crackers, flours, and doughs which has been mechanically separated from non-edible material, artificially dried and ground. If the product contains more than 3.5%

salt, the maximum percentage of salt must be a part of the name; i.e., Dried Bakery Product with \_\_\_% Salt. (Proposed 1962, Adopted 1967.)

IFN 4-00-466 Bakery waste dehydrated

60.34 Dried beans are the residue of the normal packaging and processing of \_\_\_dried beans for human consumption. This residue shall consist of the broken, small, shriveled, and cull \_\_\_beans. They shall be identified by variety such as navy, Northern, pinto, kidney, et al. Where further processing, such as grinding, roasting, etc., has occurred, ground, roasted, or other acceptable description may be part of the name, i.e., ground roasted \_\_\_dried beans. (Proposed 1976, Adopted 1977.)

IFN 5-00-594 Bean seeds

IFN 5-00-600 Bean kidney seeds

IFN 5-00-623 Bean navy seeds

IFN 5-00-624 Bean pinto seeds

60.39 Beet molasses, dried product, is the properly dried mixture of molasses and molasses dried beet pulp containing not less than 45% total sugar expressed as invert. (Proposed 1976, Adopted 1977.)

IFN 4-20-866 Beet sugar pulp with molasses dehydrated more than 45% invert sugar

60.37 Beet Pulp, dried, molasses, is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar to which has been added (beet) molasses obtained in the extraction of sugar. (Proposed 1976, Adopted 1977.)

IFN 4-00-672 Beet sugar pulp with molasses dehydrated

60.36 Beet pulp, dried, plain, is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar. (Proposed 1976, Adopted 1977.)

IFN 4-00-669 Beet sugar pulp dehydrated

60.38 Beet pulp, dried product CSF, RNS, is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar to which has been added the concentrated Steffen's filtrate obtained in the extraction of the sugar from the beets. (Proposed 1976, Adopted 1977.)

IFN 4-00-675 Beet sugar pulp with steffens filtrate dehydrated

60.27 Coastal Bermudagrass Hay is the dried aerial portion of the perennial hybrid grass, Coastal bermuda (*Cynodon dactylon*) (L.) Ja (Pers.), reasonably free of other crop plants, weeds and mold, which has been cultivated as a crop and harvested during an period of active growth. If it is fully ground, it must be designated as "Coastal Bermudagrass Meal." If it is dried by thermal means, it should be designated as "Dehydrated Coastal Bermudagrass Hay" or "Dehydrated Coastal Bermudagrass Meal." (Proposed 1971, Adopted 1972.)

IFN 1-10-609 Bermudagrass coastal dehydrated

IFN 1-00-716 Bermudagrass coastal hay

60.17 Buckwheat Hulls is the product consisting primarily of the outer covering of the buckwheat obtained in the milling of buckwheat flour. (Proposed 1963, Adopted 1968.)

IFN 1-12-238 Buckwheat hulls

60.6 Buckwheat Middlings is that portion of the buckwheat grain immediately under the hull after separation of the flour. It must contain no more hulls than is obtained in the usual process of buckwheat milling, and must contain not more than 10% crude fiber. (Adopted 1944.)

IFN 5-12-237 Buckwheat flour by-product without hulls



60.14 Cereal Food Fines consists of particles of breakfast cereals obtained as a by-product of their processing. (Adopted 1957.)  
IFN 5-01-199 Cereals food fines

\*60.33 Dehydrated Food-Waste. Any and all animal and vegetable produce picked up from basic food processing sources or institutions where food is processed. The produce shall be picked up daily or sufficiently often so that no decomposition is evident. Any and all undesirable constituents shall be separated from the material. It shall be dehydrated to a moisture content of not more than 12% and be in a state free from all harmful micro-organisms. (Proposed 1975, Adopted 1976.)

IFN 4-12-175 Food waste dehydrated

\*60.12 Dehydrated Garbage is composed of artificially dried animal and vegetable waste collected sufficiently often that harmful decomposition has not set in, and from which have been separated crockery, glass, metal, string, and similar materials. It must be processed at a temperature sufficient to destroy all organisms capable of producing animal diseases. If part of the grease and fat is removed, it must be designated as "Degreased Dehydrated Garbage." (Adopted 1954, Amended 1963.)

IFN 4-02-092 Garbage dehydrated

60.29 Gelatin By-Products is the dried residue from the various process streams from the manufacture of edible gelatin. The total crude protein content will contain a minimum of 85% digestible protein as determined by the AOAC pepsin method 22.025-22.031. A 25% maximum of diatomaceous earth will not be exceeded. This product is for use in poultry feeds not to exceed 5% of the total rations. (Proposed 1972, Adopted 1973.)

IFN 5-14-503 Gelatin process residue

60.11 Ground Grass is obtained by drying and grinding grass which has been cut before formation of the seed. If a specie name is used, the produce must correspond thereto. (Adopted 1949, Amended 1964.)

IFN 1-02-215 Grass hay sun-cured ground

60.18 Guar Meal is obtained from whole guar beans after removal of most of the endosperm. If the product is heat treated, it may be designated as "heat treated" or "toasted". (Proposed 1966, Adopted 1968.)

IFN 5-05-687 Guar seeds without endosperm ground

60.19 Dried Kelp is dried seaweed of the families Laminariaceae and Fucaeae. The maximum percentage of salt (NaCl) and the minimum percentage of potassium (K) must be declared. If the kelp is sold as a source of iodine (I), the minimum percentage of iodine must be declared. If the product is prepared by artificial drying, it may be called "Dehydrated Kelp." (Proposed 1966, Adopted 1968.)

IFN 1-08-073 Seaweed kelp whole dehydrated

60.24 Paunch Product, Dehydrated is a product composed of the contents of the rumen of slaughtered cattle, dehydrated at temperatures over 100° centigrade to a moisture content of 12% or less, such dehydration designed to destroy any pathogenic bacteria. It shall be dehydrated promptly after removal from the rumen to prevent decomposition. (Proposed 1969, Adopted 1970.)

IFN 1-09-327 Animal rumen contents dehydrated

60.28 Dried Potato Products is the dried residue of potato pieces, peeling, culls, etc., obtained from the manufacture of processed potato products for human consumption. The residue may contain up to 3% hydrate of lime which may be added to aid in processing. (Proposed 1972, Adopted 1973.)

IFN 4-03-775 Potato process residue dehydrated

60.20 Dehydrated Silage (ensilage) Pellets are pellets made from wholesome silage (ensilage) which has been dried by thermal means and formed into pellets by compacting and forcing through die openings by a mechanical process. The product should bear a name descriptive of the type of silage (ensilage) pelleted, such as "Dehydrated Alfalfa Silage (ensilage) Pellets," etc. (Proposed 1967, Adopted 1968.) IFN 3-08-812 Alfalfa silage dehydrated pelleted

60.41 Concentrated Steffen Filtrate (CSF) is obtained as a by-product of the recovery of sucrose from beet molasses by utilization of the Steffen process (precipitation with calcium oxide). (Proposed 1978, Adopted 1979.)  
IFN 5-00-679 Beet sugar steffens filtrate condensed

60.10 Ground Straw is the ground product remaining after separation of the seed from mature forage plants. The source of the material shall constitute a part of the name of the product, i.e., "Ground Blue Grass Straw", "Ground Alfalfa Straw". (Adopted 1948, Amended 1964.)

IFN 1-04-682 Cereals straw ground

IFN 1-12-232 Alfalfa straw ground

IFN 1-12-233 Bluegrass straw ground

60.35 Sugar Foods By-Product is the product resulting from the grinding and mixing of the inedible portions derived from the preparation and packaging of sugar based food products such as candy, dry packaged drinks, dried gelatin mixes, and similar food products which are largely sugar. It shall contain not less than 80% total sugar expressed as invert. It shall be free from foreign materials harmful to animals. (Proposed 1976, Adopted 1977.)

IFN 4-20-865 Sugar foods process residue

60.8 Dried Tomato Pomace is the dried mixture of tomato skins, pulp, and crushed seeds. If the pomace contains spices used in the production of the tomato product, this must be shown in the name as "Dried Spiced Tomato Pomace." (Adopted 1953, Amended 1964.)

IFN 5-05-041 Tomato pomace dehydrated

60.9 Yeast Dried Grains is the properly dried residue from the mixture of cereals, malt, and malt sprouts (sometimes cottonseed meal) obtained in the manufacture of yeast or vinegar, and consists of corn or corn and rye from which most of the starch has been extracted, together with malt added during the manufacturing process to change the starch to sugar, and malt sprouts (sometimes cottonseed meal) added during the manufacturing process to aid in filtering the residue from the wort and to serve as a source of food supply for the yeast. If residue is from manufacture of vinegar, may also be listed as "Vinegar Dried Grains." (Adopted prior to 1928.)

IFN 5-02-158 Cereals vinegar fermentation grains dehydrated

IFN 5-02-159 Cereals yeast fermentation grains dehydrated

60.73 Salts of Volatile Fatty Acids is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids/isovaleric, 2-methylbutyric, and n-valeric. The contained ammonium or calcium salts of volatile fatty acids shall conform to the specifications in 21 CFR 573.914. It is used as a source of energy in dairy cattle feed. The label of the product shall bear adequate directions for use including statements expressing maximum use levels: For ammonium salts of volatile fatty acids--not to exceed 120 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy; For calcium salts of volatile fatty acids--not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy. (Proposed 1985, Adopted 1986.) Reg. 21CFR 573.914

60.74 **Tapioca/Manioca and Cassava Root** is the whole root chipped mechanically into small pieces and sun dried on concrete surfaces for 2 to 3 days and then the chips are pelleted. (Adopted 1993)

IFN 4-18-896 Cassava Tubers, Sun-cured Pelleted

60.75 **Ethyl Alcohol Containing Ethyl Acetate** is a product containing not less than 92.5% ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100% ethyl acetate. It is used in ruminant feed supplements as a source of added energy. (Proposed 1986, Adopted 1990) Reg. 21CFR 584.200

IFN 4-18-895 Ethyl Alcohol-Ethyl Acetate

60.76 **Dried Seaweed Meal** is the product resulting from drying and grinding non-toxic macroscopic marine algae (marine plants) of the following botanical divisions: Division RHODOPHYTA (Red Algae); Division PHAEOPHYTA (Brown Algae); Division CHLOROPHYTA (Green Algae). The maximum percentage of salt (NaCl) (determined by sodium content), the minimum percentage of potassium (K), and the percentage of iodine (I) shall be guaranteed. If the product is prepared by artificial drying it must be labeled as: Dehydrated Seaweed Meal. The family(ies) shall be identified on the label.

Note: The following families are accepted for use under the definition, Dried Seaweed Meal: RHODOPHYTA (Red Algae): Gelidiaceae, Endocodiaceae, Gigartiniaceae, Gracilariaceae, Phyllophoraceae, Solieriaceae, Hypnaceae, Palmariaaceae, Bangiaceae; PHAEOPHYTA (Brown Algae): Chordaceae, Laminiaceae, Lessoniaceae, Alariaceae, Fucaaceae, Sargassaceae, Durvillaceae; CHLOROPHYTA (Green Algae): Monostromataceae, Ulvaceae. (Proposed 1986, Adopted 1991, Amended 1994)

IFN 5-18-897 Algae Whole Meal

60.78 **Sweet Lupin Meal** is the product resulting from the grinding of the entire seed of the species of *Lupinus albus* (white), *L. angustifolius* (blue), or *L. luteus* (yellow) which contain less than 0.03% alkaloids. (Proposed 1993, Adopted 1996)

60.79 **Sweet Lupin Meal Dehulled** is the product resulting from the grinding of seeds after mechanical removal of the hulls from the species of *Lupinus albus* (white), *L. angustifolius* (blue), or *L. luteus* (yellow) which contain less than 0.03% alkaloids. (Proposed 1993, Adopted 1996)

60.80 **Sweet Lupin Meal Solvent Extracted** is the product obtained by grinding of the flakes after the removal of most of the oil by a solvent extraction process from the seeds of the species of *Lupinus albus* (white), *L. angustifolius* (blue), or *L. luteus* (yellow) which contain less than 0.03% alkaloids. It must contain not more than 7% crude fiber. (Proposed 1993, Adopted 1996)

Note: The sweet lupin species defined above are of Mediterranean origin and are quite distinct from the Lupine's of North America. The two differ evolutionarily and genetically in their origin and thus the sweet lupin cannot be 'contaminated' by outcrossing with the North American lupine.

60.81 **Concentrated Separator By-Product (CSR)** is obtained as a by-product of the recovery of sucrose from beet molasses by utilization of molecular exclusion chromatography. (Proposed 1991, Adopted 1993)

IFN 5-32-051 Beet, Sugar, separator by-product, condensed

60.83 **Beet Fiber, dried**, plain is the refined plant material derived from sugar beet pulp after sugar extraction which has been further refined by washing, drying and milling. It shall contain a total dietary fiber (crude fiber) content of not less than 80% and an ash content of not more than 3%. (Proposed 1991, Adopted 1993)

IFN 1-32-188 Beet, Sugar-Fiber, Dehydrated

60.84 **Psyllium Seed Husk** is the cleaned, dried seed coat separated by winnowing and thrashing of psyllium seeds. It is to be used as a source of dietary fiber and the crude fiber level must be declared on the label. (Proposed 1991, Adopted 1993)

IFN 1-32-187 Plantago seed husk

60.86 **1, 3-Butylene Glycol (1, 3-Butanediol)** is a viscous, colorless liquid of 99% purity, with a specific gravity at 20/20 degrees centigrade: 1.004 to 1.006, and has a distillation range of 200-215 degrees centigrade. It is to be used as a source of energy in swine feed at a level not to exceed 9% of the dry matter of the total ration. It should be thoroughly mixed in feed, not less than 5 minutes after its addition, with equipment adapted for the addition of liquids. (Reference 21 CFR 573.225 and 21 CFR 173.220. (Proposed 1992, Adopted 1996)

60.93 **Pasta Product** is a mixture of dry, whole and broken particles of noodles, macaroni, spaghetti, etc., or a mixture of these resulting from the manufacturing and packaging of edible pasta products and which has been mechanically separated from any non-edible materials. (Proposed 1995, Adopted 1996)

\*The words "Mechanical Extracted" or "Solvent Extracted" are not required when listed as an ingredient in a manufactured feed.

#### Tentative

T60.88 **Corn Refinery Concentrate (CRC)** is the concentration of sweetwaters, by filtration and evaporation, which are by-products in the production of corn syrup. The total sugars expressed as invert and the moisture level shall be guaranteed. (Proposed 1993)

T60.94 **Potato Protein**. Potato Protein is derived from de-starched potato juice from which the proteinaceous fraction has been precipitated by thermal coagulation followed by dehydration. (Proposed 1996)

T60.95 **Lablab** (Lablab purpureus or Dolichos lablab) also known as hyacinth bean, is an annual legume that produces forage as either hay or pasture for ruminants. Leaves and/or stems can be used as a feed ingredient if it is free of mature seed. (Proposed 1997)

T60.98 **L-Carnitine** is a nutritional supplement with a minimum content of 97.0% L-Carnitine and a maximum of 0.5% D-isomer. L-Carnitine is for use in swine feeds at levels not to exceed 0.1% (1000 ppm) of complete feed, for use in fish feed at levels not to exceed 0.25% (2500 ppm) of complete feed, and for use in dog feeds at levels not to exceed 0.075% (750 ppm) of complete feed on a dry matter basis. (Proposed 1997, Amended 1999)

T60.96 \* **Food Processing Waste** is composed of any and all animal and vegetable products from basic food processing. This may include manufacturing or processing waste, cannery residue, production over-run, and otherwise unsalable material. The guaranteed analysis shall include the maximum moisture, unless the product is dried by artificial means to less than 12% moisture and designated as "Dehydrated Food Processing Waste." If part of the grease and fat is removed, it must be designated as "Degreased". (Proposed 1998)

T60.97 \* **Restaurant Food Waste** is composed of edible food waste collected from restaurants, cafeterias, and other institutes of food preparation. Processing and/or handling must remove any and all undesirable constituents including crockery, glass, metal, string, and similar materials. The guaranteed analysis shall include maximum moisture, unless the product is dried by artificial means to less than 12% moisture and designated as "Dehydrated Restaurant Food Waste." If

part of the grease and fat is removed it must be designated as "Degreased". (Proposed 1998)

**T6099 Chia Seed** consists of cleaned, sound, dry, whole seed of the chia plant (*Salvia hispanica*). Typically it contains 18% crude protein, 32% crude fat and 32% crude fiber. (Proposed 1998)

### 63. MOLASSES

Investigator and Section Editor—Hershel Morris, LA

#### Official

**63.1 Beet Molasses** is a by-product of the manufacture of sucrose from sugar beets. It must contain not less than 48% total sugars expressed as invert and its density determined by double dilution must not be less than 79.5 Brix. (Adopted 1941, Amended 1960.)

IFN 4-30-289 Beet sugar molasses

**63.3 Citrus Molasses** is the partially dehydrated juices obtained from the manufacture of dried citrus pulp. It must contain not less than 45% total sugars expressed as invert and its density determined by double dilution must not be less than 17.0 Brix. (Adopted 1952, Amended 1960.)

IFN 5-01-241 Citrus syrup

**63.5 Hemicellulose Extract** is a by-product of the manufacture of pressed wood. It is the concentrated soluble material obtained from the treatment of wood at elevated temperature and pressure without use of acids, alkalis, or salts. It contains pentose and hexose sugars, and has a total carbohydrate content of not less than 55%. (Proposed 1965, Adopted 1966.) Reg. 573.520

IFN 4-08-030 Hemicellulose extract

**63.6 Starch Molasses** is a by-product of the manufacture of dextrose from starch derived from corn or grain sorghums in which the starch is hydrolyzed by use of enzymes and/or acid. It must contain not less than 43% reducing sugars expressed as dextrose and not less than 50% total sugars expressed as dextrose. It shall contain not less than 73% total solids. (Proposed 1967, Adopted 1968.)

IFN 4-08-037 Maize-sorghum grain starch molasses

**63.7 Cane Molasses** is a by-product of the manufacture of sucrose from sugar cane. It must contain not less than 43% total sugars expressed as invert. If its moisture content exceeds 27%, its density determined by double dilution must not be less than 79.5 Brix. (Proposed 1973, Adopted 1987.)

IFN 4-13-251 Sugarcane molasses

### 66. NON-PROTEIN NITROGEN

Investigator and Section Editor—Sharon Berz, FDA

#### Official

**66.1 Urea** is predominantly urea but may contain other non-toxic nitrogenous compounds which are present as by-products from the commercial synthesis and processing of Urea. It must contain not less than 45% nitrogen (equivalent to 281.25% crude protein). If it contains less than 45% N but 41% or more N, it must be designated as "Urea and Conditioner(s)". If the name of the conditioner(s) does not appear in the product name, the ingredient listing must contain the specific name of the conditioner(s).

If the Urea and Conditioner(s) contribute more than 0.5% conditioner(s) to the mixed feed, the conditioner(s) must be named in the mixed ingredient list. (Proposed 1958, Amended 1962, 1963, 1964, Adopted 1968.)

IFN 5-05-070 Urea 45% nitrogen 281% protein equivalent

**66.2 Feed Grade Biuret** is predominantly composed of biuret (55% minimum) together with related non-toxic nitrogenous compounds resulting from the controlled pyrolysis of urea and subsequent processing. It must contain not less than 35% nitrogen (equivalent to 218.7% crude protein) with not more than 15% nitrogen (equivalent to 93.75% crude protein) being from urea. It shall not contain more than 0.5% mineral oil.

The label of the additive and of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom, must contain the following information in addition to any other required information:

- (1) The name of the additives
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide:

(a) The diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of non-protein nitrogen exceed one-third of the total crude protein in the total daily ration.

(b) Use only in mixed feeds for ruminants (cattle, sheep and goats.)

(4) Warning: Do not feed to animals producing milk for human consumption. This feed should be used only in accordance with directions furnished on the label. (Proposed 1972, Adopted 1974, Amended 1975.) Reg. 573.220 IFN 5-09-824 Biuret

**66.3 Gelatinized Starch-Urea Product** is obtained by processing a mixture of finely ground grains or other carbohydrate containing materials with urea under regulated conditions of temperature (250 to 250° F), moisture (15 to 30%) and pressure (400 to 500 p.s.i.). It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed twenty-five percent of the total ration.

The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

- (1) The name of the additive
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than twenty-five percent of the additive in the total ration and a prominent statement:

"Warning—This feed should be used in accordance with the directions furnished on the label." (Proposed 1972, Adopted 1975.)

IFN 5-14-506 Starch-urea product gelatinized

**66.4 Liquid Starch-Controlled Urea Product** is obtained by processing a slurry of finely ground grains or other carbohydrate-containing materials with urea in a hydroheater under regulated conditions of temperature (250° to 350° F), moisture (50 to 70%) and pressure (15 to 150 p.s.i.). It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed twenty-five percent of the total ration.

The label of the additive and of any feed additive supplement, feed additive concentrate or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

- (1) The name of the additive
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than twenty-five percent of the additive in the total ration and a prominent statement: "WARNING—This feed should be used only in accordance with the directions furnished on the

label."

(Proposed 1978, Adopted 1980.)

IFN 5-30-264 Starch-urea product liquid

66.5 Fermented Ammoniated Condensed Whey is the product produced by the Lactobacillus bulgaricus fermentation of whey with the addition of ammonia. It must contain 35% to 55% crude protein and not more than 42% equivalent crude protein from non-protein nitrogen. It is to be used as a source of crude protein and non-protein nitrogen for cattle.

The label of the additive and of any feed additive supplement, feed additive concentrate or feed additive premix prepared therefrom must contain the following information in addition to any other required information:

(1) The name of the additive.  
(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for storage and use:

(a) Store in closed vented tank equipped for agitation. Agitate five (5) minutes before using. Do not store at temperatures above 110° F (43° C).

(b) Mix with grain, roughage, or grain and roughage prior to feeding or as a component of free choice liquid feeds, used to supplement the diets of cattle fed other sources of nutrients. Fermented ammoniated condensed whey shall not exceed 80% of free choice liquid feed.

(c) The maximum equivalent crude protein from fermented ammoniated condensed whey and equivalent crude protein from all other added forms of non-protein nitrogen shall not exceed 30% of the dietary crude protein.

(4) A prominent statement: "CAUTION--This feed should be used only in accordance with the directions furnished on the label." (Proposed 1979, Amended 1980, Adopted 1981, Amended 1983.) Reg. 573.450

IFN 5-28-223 Cattle whey fermented ammoniated condensed

66.6 Ammonium Chloride, is the product resulting from the neutralization of hydrochloric acid with ammonia generally expressed as  $\text{NH}_4\text{Cl}$ . It must contain not less than 25.6% nitrogen (equivalent to 160% crude protein). It must contain not more than 0.1% moisture, 0.4% salt ( $\text{NaCl}$ ), 15 ppm iron (Fe), 3 ppm arsenic (As), and 10 ppm heavy metals reported as lead. It may be treated with not more than 1.0% tricalcium phosphate to prevent caking. It shall not be made from by-product ammonia recovered from coke oven gas. It is to be used only in feeds for cattle and sheep as a source of non-protein nitrogen at a level not to exceed 1.0% ammonium chloride in the total daily ration to provide not more than 1.6% equivalent crude protein. Labels for feed containing ammonium chloride include premixes, concentrates and supplements shall contain adequate directions for use and the following prominent statements: "CAUTION: Use only as directed. For ruminants (cattle and sheep) only." (Adopted 1984.)

IFN 8-08-814 Ammonium Chloride

# NOTES

Diammonium Phosphate

See Definition 57.16 in Mineral Products Section; Diammonium Phosphate as source of Non-Protein Nitrogen.

Ammonium Polyphosphate Solution

See Definition 57.22 in Mineral Products Section; Ammonium Polyphosphate Solution as source of Non-Protein Nitrogen.

Ammoniated Rice Hulls

See Definition 87.7 in Special Purpose Products Section; Ammoniated Rice Hulls as a source of Non-Protein Nitrogen.

Ammoniated Cottonseed Meal

See Definition 87.9 in Special Purpose Products Section; Ammoniated Cottonseed Meal as source of Non-Protein Nitrogen.

Ammonium Sulfate

See Definition 57.27 in Mineral Products Section; Ammonium Sulfate as source of Non-Protein Nitrogen.

Anhydrous Ammonia

See Definition 87.11 in Special Purpose Products Section; Anhydrous ammonia as source of Non-Protein Nitrogen.

Monammonium Phosphate

See Definition 57.33 in Mineral Products Section Mono-Ammonium Phosphate as source of Non-Protein Nitrogen.

## 69. OAT PRODUCTS

Investigator and Section Editor--Paul M. Bachman, MN

### Official

69.1 Oat Groats are cleaned oats with the hulls removed. (Adopted 1931, Amended 1963.)

IFN 4-03-331 Oats groats

69.2 Oat Hulls consists primarily of the outer covering of oats, obtained in the milling of table cereals or in the groating of oats from clean oats. (Adopted prior to 1928, Amended 1963.)

IFN 1-03-281 Oats hulls

69.3 Feeding Oat Meal is obtained in the manufacture of rolled oat groats or rolled oats and consists of broken oat groats, oat groat chips, and floury portions of the oat groats, with only such quantity of finely ground oat hulls as is unavoidable in the usual process of commercial milling. It must not contain more than 4% crude fiber. (Adopted 1938.)

IFN 4-03-303 Oats cereal by-product less than 4% fiber

69.4 Clipped Oat By-Product is obtained in the manufacture of clipped oats. It may contain the light chaffy material broken from the end of the hulls, empty hulls, light immature oats, and dust. It must not contain an excessive amount of oat hulls. (Adopted prior to 1928.)

IFN 1-03-269 Oats grain clipped by-product

69.6 Mixed Feed Oats consists of a mixture of grain containing at least 30% of cultivated oats provided that the mixture consists of either (a) not less than 65% of cultivated and wild oats combined or (b) not less than 65% of wild oats. It must contain more than 25% of other grains, not more than 6% heat damaged kernels of oats, wild oats, and other grains, and not more than 10% foreign material which may include 4% fine seeds. (Adopted 1958, Amended 1964.)

IFN 4-08-026 Oats wild-oats grain

NOTE: Foreign material must be all matter except wild oats and grains for which standards have been established under the United States Grain Standards Act.

69.7 Oat Mill By-Product is the by-product obtained in the manufacture of oat groats, consisting of oat hulls, and particles of the groat, and containing not more than 25% crude fiber. (Proposed 1963, Adopted 1964.)

IFN 1-03-332 Oats groats by-product less than 22% fiber

71. OTHER OILSEED PRODUCTS  
Investigator and Section Editors—Shannon Jordre, SD  
and Ricky Schroeder, TX

Official

71.77 Canola Meal low erucic acid low glucosinolate consists of the meal obtained after the removal of most of the oil, by a direct solvent or prepress solvent extraction process, from the whole seeds of the species *Brassica napus* or *Brassica campestris* the oil component of which seed contains less than two percent erucic acid and the solid component of which seed contains less than 30 micromoles of any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate and 2-hydroxy-4-pentenyl glucosinolate per gram of air dry, oil free solid. It must contain a maximum of 12% crude fiber and a maximum of 30 micromoles of glucosinolates per gram.

Note: A method of analysis for glucosinolates is contained in the publication by J.K. Daun and D.I. McGregor, December 15, 1981, Glucosinolate Analysis of Rapeseed (Canola). Method of the Canadian Grain Commission, Grain Research Laboratory. (The method is on file with the Feed Methods Clearinghouse, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration. (Proposed 1987, Adopted 1991, Amended 1995, Adopted 1998)

IFN 5-05-145 Canola Meal Prepress Solvent Extracted, Low Erucic Acid, Low Glucosinolate

IFN 5-05-146 Canola Meal Solvent Extracted, Low Erucic Acid, Low Glucosinolate

\*71.60 Coconut Meal, Mechanical Extracted, is the ground residue which remains after removal of most of the oil from dried meat of coconuts by a mechanical extraction process. May also be called "Copra Meal". (Adopted 1955, Amended 1963, 1968.)

IFN 5-01-572 Coconut kernels with coats meal mechanical extracted

\*71.61 Coconut Meal, Solvent Extracted, is the ground residue which remains after removal of most of the oil from dried meat of coconuts by a solvent extraction process. May also be called "Copra Meal". (Adopted 1955, Amended 1963, 1968.)

IFN 5-01-573 Coconut kernels with coats meal solvent extracted

71.62 Crambe Meal, Heat Toasted is the seed meal of *Crambe abyssinica* after the removal of oil from the seed and hull by pre-press solvent extraction or by solvent extraction alone. The resulting seed meal is heat toasted. It shall conform to the restriction of glucosinolate, goitrin, and nitrogen soluble as set forth in 21 CFR 573, Section 310. It shall have a crude protein, crude fat, and a crude fiber guarantee. Myrosinase enzyme activity shall be absent. It is used or intended for use in the feed of feedlot cattle as a source of protein in an amount not to exceed 4.2 percent of the total ration. (Proposed 1982, Adopted 1983.) Reg. 21CFR 573.310

IFN 5-16-280 Crambe abyssinica seeds meal solvent extracted toasted

\*71.1 Linseed Meal, Mechanical Extracted, is the product obtained by grinding the cake or chips which remain after removal of most of the oil from flaxseed by a mechanical extraction process. It must contain no more than 10% fiber. (Adopted 1943, Amended 1947, 1949, 1960, 1961, 1964, 1968.)

IFN 5-30-287 Flax seeds meal mechanical extracted

\*71.11 Linseed Meal, Solvent Extracted, is the product obtained by grinding the flakes which remain after removal of most of the oil from flaxseed by a solvent

extraction process. It must contain no more than 10% fiber. (Adopted 1943, Amended 1947, 1949, 1960, 1961, 1964, 1968.)

IFN 5-30-288 Flax seeds meal solvent extracted

\*71.2 Flaxseed Screenings Meal, Solvent Extracted, is the ground product obtained after solvent extraction of part of the oil from the smaller imperfect flaxseeds, weedseeds, other oilseeds and other foreign material having feeding value, separated in cleaning flaxseed. (Adopted 1943, Amended 1962, 1964, 1968)

IFN 5-12-228 Flax seed screenings meal solvent extracted

71.3 Flax Plant Product is that portion of the flax plant having feeding value remaining after harvesting the seed and separation of the base fibers and flax shives. It consists of the leaves, corticle tissues, flax seed bolls, broken and immature flax seeds. It must contain a minimum of 9% crude protein and a maximum of 35% crude fiber. (Adopted 1957.)

IFN 1-12-230 Flax fiber process residue dehydrated

71.4 Flax Straw By-Product is the ground product remaining after the removal of the longer fiber material from flax straw by mechanical processing. It must contain not less than 2% crude protein and not more than 70% crude fiber. (Proposed 1964, Adopted 1968.)

IFN 1-12-229 Flax straw fiber process residue ground

\*71.30 Mustard Meal, Solvent Extracted is the product obtained by grinding the cake which remains after removal of some of the oil by mechanical extraction, and removing most of the remaining oil by solvent extraction. Obtained from the seed of cultivated mustard plants (*Brassica* sp.) (Proposed 1972, Adopted 1973.)

IFN 5-12-149 Mustard seeds meal solvent extracted

Rations should be restricted to cattle and sheep and not contain more than 10% for cattle and 10% for sheep. It should not be fed to lactating dairy cows if milk production is for human consumption because of objectionable taste and/or odor.

71.21 Peanut Skins is the outer covering of the peanut kernel, exclusive of hulls, as obtained in ordinary commercial processing. The product may contain broken peanut kernels. (Adopted 1946, Amended 1964.)

IFN 1-03-631 Peanut seed coats

71.6 Peanut Hulls consists of the outer hull of the peanut shell. (Proposed 1965, Adopted 1966.)

IFN 1-08-028 Peanut pods (hulls)

\*71.7 Peanut Meal and Hulls, Mechanical Extracted and Solvent Extracted is a product of shelled peanuts, composed principally of the kernels and hulls, with such portion of the oil, as may be left in the ordinary course of manufacture. (Adopted 1978.)

IFN 5-03-655 Peanut pods with seeds meal mechanical extracted

IFN 5-03-656 Peanut pods with seeds meal solvent extracted

71.8 Ground Peanut Hay is composed of ground peanut leaves and stems from which the peanuts have been removed. (Proposed 1976.)

IFN 1-03-627 Peanut hay sun-cured ground

\*71.9 Peanut Meal, Mechanical Extracted and Solvent Extracted is a ground product of the shelled peanuts, composed principally of the kernels, with such portion of the hull, or fiber, and oil as may be left in the ordinary course of manufacture. It must contain no more than 7% crude fiber. (Adopted 1978.)

IFN 5-03-649 Peanut seeds without coats meal mechanical extracted

IFN 5-03-650 Peanut seeds without coats meal solvent extracted

\*71.25 **Rapeseed Meal, Mechanical Extracted**, Rapeseed meal, mechanical extracted, obtained by grinding the cake which remains after removal of most of the oil by mechanical extraction of the seed from the rapeseed plant (Brassica). It must contain a minimum of 32% protein and a maximum of 12% crude fiber. (Proposed 1970, Adopted 1971.)

IFN 5-03-870 Rape seeds meal mechanical extracted

\*71.130 **Safflower Meal, Mechanical Extracted**, is the ground residue obtained after extracting the oil from whole safflower seed by a mechanical extraction process. (Adopted 1954, Amended 1964, 1968.)

IFN 5-04-109 Safflower seeds meal mechanical extracted

\*71.131 **Safflower Meal, Solvent Extracted**, is the ground residue obtained after extracting the oil from whole safflower seed by a solvent extraction process. (Adopted 1954, Amended 1964, 1968.)

IFN 5-04-110 Safflower seeds meal solvent extracted

71.23 **Sunflower Hulls** consists of the outer covering of sunflower seed. (Proposed 1967, Adopted 1968.)

IFN 1-04-720 Sunflower hulls

\*71.210 **Sunflower Meal, Dehulled, Mechanical Extracted**, is obtained by grinding the residue remaining after the extraction process. (Proposed 1967, Adopted 1969.)

IFN 5-30-033 Sunflower seeds without hulls meal mechanical extracted

\*71.211 **Sunflower Meal, Dehulled, Solvent Extracted**, is obtained by grinding the residue remaining after extraction of most of the oil from dehulled sunflower seed by a solvent extraction process. (Proposed 1967, Adopted 1969.)

IFN 5-30-034 Sunflower seeds without hulls meal solvent extracted

\*71.220 **Sunflower Meal, Mechanical Extracted**, is obtained by grinding the residue remaining after extraction of the oil from whole sunflower seed by a mechanical extraction process. (Proposed 1967, Adopted 1969.)

IFN 5-27-477 Sunflower seeds meal mechanical extracted

\*71.221 **Sunflower Meal, Solvent Extracted**, is obtained by grinding the residue remaining after extraction of most of the oil from whole sunflower seed by a solvent extraction process. (Proposed 1967, Adopted 1969.)

IFN 5-30-032 Sunflower seeds meal solvent extracted

\*The words "Mechanical Extracted" or "Solvent Extracted" are not required when listed as an ingredient in a manufactured feed.

#### 74. RECYCLED ANIMAL WASTE PRODUCTS

Investigator and Section Editor--Oecil Williams, NC

Any person seeking or receiving registration of any processed animal waste product shall test, by representative sampling and assaying of such samples, and keep accurate records thereof, the processed animal waste product for which the registration is sought or received. The sample shall be of sufficient size so as to provide meaningful data, statistically reliable in carrying out the purpose of such sampling and analysis.

The registrant, manufacturer, or producer of any such processed animal waste product ingredient shall conform to the following sample and assay requirements, in addition to quality standards, testing on the same production run of lots:

- Drugs suspected or known to be used in the feed or as a therapeutic treatment of source animals.
- Pesticides used on the source animal, facility, and wastes for pest control.

trial.

- Pathogenic organisms, at least to include *Salmonella* and *E. coli*.
- Heavy metals: arsenic, cadmium, copper, lead, mercury and selenium, at least.
- Parasitic larva or ova.
- Mycotoxins, such as aflatoxins.

Periodic analyses shall be conducted on production runs no less than one per calendar quarter, except that less frequent testing may be allowed where analytical results show continued uniformity and a consistent margin of compliance. Any processed animal waste product that does not meet the quality standards for the product shall be further processed until standards are met, or shall be diverted to non-feed uses or destroyed.

If a product contains drug residues, then the label shall contain the following statement in bold face type:

**"WARNING: THIS PRODUCT CONTAINS DRUG RESIDUES. DO NOT USE WITHIN 15 DAYS OF SLAUGHTER AND DO NOT USE 15 DAYS PRIOR TO OR DURING THE FOOD PRODUCTION PERIOD OF DAIRY ANIMALS AND LAYING HENS."**

If the product contains 25 ppm or greater of copper, a maximum guarantee of copper and the following statement in bold face type is required:

**"WARNING: CONTAINS HIGH LEVELS OF COPPER. DO NOT FEED TO SHEEP."**

Any person seeking or receiving registration of any processed animal waste product shall keep for a period of two years, accurate records of:

- All sources of raw materials and date acquired, including information on drug and pesticide usage.
- All production output, including a code or other method to identify the date of production.
- All sales and distribution, including the name and address of the purchaser or to whom distributed, date, quantity and product code.
- Sample and assay records of testing specified above.

Product definitions--Processed animal waste products as a class, offered for sale or distributed for sale, shall not contain extraneous materials such as, but not limited to, metal, glass, nails or other harmful matter. They shall be free of harmful pathogenic organisms, pesticide residues, parasites, or drug residues, above levels permitted by State or Federal statute or regulation, which could be harmful to animals or could result in residues in human food products or by-products of animals at levels in excess of those allowed by State or Federal statute or regulation.

74.1 **Dried Poultry Waste--(DPW)** means a processed animal waste product composed primarily of feces from commercial poultry, which has been thermally dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 18.0% crude protein, and not more than 15.0% crude fiber, 30.0% ash, and 1.0% feathers. (Adopted 1982.)

IFN 4-07-253 Poultry manure nonprotein nitrogen extracted dehydrated

74.2 **Dried Poultry Waste--NPN Extracted** means a processed animal waste product composed primarily of feces from commercial poultry which has been processed to remove part or all of the equivalent crude protein, NPN as urea and/or uric acid and which has been thermally dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 11.0% crude protein, and not more than 15.0% crude fiber, 30.0% ash, and 1.0% feathers. (Adopted 1982)

IFN 4-07-255 Poultry manure nonprotein nitrogen extracted dehydrated

IFN 4-03-930 Rice bran with germ meal solvent extracted

75.4 Chipped Rice, Broken Rice, or Brewers Rice is the small fragments of rice kernels that have been separated from the larger kernels of milled rice. (Proposed 1959, Adopted 1960.)

IFN 4-03-932 Rice groats polished broken

75.5 Ground Brown Rice is the entire product obtained in grinding the rice kernels after the hulls have been removed. (Proposed 1959, Adopted 1960.)

IFN 4-03-935 Rice groats ground

75.6 Rice Hulls consists primarily of the outer covering of the rice. (Proposed 1959, Adopted 1960.)

IFN 1-08-075 Rice hulls

75.7 Rice Bran is the pericarp or bran layer and germ of the rice, with only such quantity of hull fragments, chipped, broken, or brewers rice, and calcium carbonate as is unavoidable in the regular milling of edible rice. It must contain not more than 13% crude fiber. When the calcium carbonate exceeds 3% (Ca-1.2%), the percentage must be declared in the brand name; i.e., Rice Bran with Calcium Carbonate not exceeding \_\_\_\_%. (Proposed 1963, Adopted 1964.)

IFN 4-03-928 Rice bran with germs

75.8 Rice Mill By-Product is the total offal obtained in the milling of rice. It consists of rice hulls, rice bran, rice polishings and broken rice grains. Its crude fiber content must not exceed 32%. (Proposed 1961, Adopted 1965.)

IFN 1-03-941 Rice mill run NOTE: See also 87.6 and 87.7

75.9 Parboiled Rice Bran is about 5 to 7% by weight of Parboiled Rough Rice and is a mixture made up of a combination of several botanical tissues: pericarp, seed coat, nucellus, and the outermost portion of the endosperm (the aleurone layer). It may contain hull fragments, broken grains and traces of added calcium carbonate as is unavoidable in the milling of parboiled rice. (Proposed 1992, Adopted 1996)

75.10 Stabilized Rice Bran is rice bran which has been treated soon after milling by heat or other means that will substantially reduce the lipase activity. Free fatty acid content of the crude fat extracted shall not exceed four percent. (AOAC 940.28) (Proposed 1995, Adopted 1996)

## 78. RYE PRODUCTS

Investigator and Section Editor—Ken Jackson, NE  
Official

78.1 Rye Mill Run is obtained in the usual process of the milling of rye flour from cleaned and scoured rye, consisting principally of the mill-run of the outer covering of the rye kernel and the rye germ with small quantities of rye flour and aleurone, and must not contain more than 9.5% crude fiber. (Adopted 1946.)

IFN 4-04-034 Rye mill run less than 9.5% fiber

78.2 Rye Middlings consist of rye feed and rye red dog combined in the proportions obtained in the usual process of milling rye flour, and must not contain more than 8.5% crude fiber. (Adopted 1946.)

IFN 4-04-031 Rye flour by-product less than 8.5% fiber

## 81. SCREENINGS

Investigator and Section Editor—Michael Cooper, ID  
Official

Screenings is obtained in the cleaning of grains which are included in the United States Grain Standard Act and other agricultural seeds. It may include

74.3 Dried Poultry Litter—(DPL) means a processed animal waste product composed of a processed combination of feces from commercial poultry together with litter that was present in the floor production of poultry, which has been artificially dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 18.0% crude protein; and not more than 25.0% crude fiber, 20.0% ash, and 4.0% feathers. (Adopted 1982.)

IFN 5-05-587 Poultry manure and litter dehydrated

74.4 Dried Ruminant Waste—(DRW) means a processed animal waste product composed primarily of processed ruminant excreta which has been artificially dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 12.0% crude protein, and not more than 40.0% crude fiber, including straw, woodshavings, etc., and not more than 30.0% ash. (Adopted 1982.)

IFN 1-07-526 Animal manure dehydrated

74.5 Dried Swine Waste—(DSW) means a processed animal waste product composed primarily of swine excreta which has been artificially dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 20.0% crude protein, not more than 35.0% crude fiber, including other material such as straw, woodshavings, or acceptable other bedding materials, and not more than 20.0% ash. (Adopted 1982.)

IFN 5-02-790 Swine manure dehydrated

74.6 Undried Processed Animal Waste Products—means a processed animal waste product composed of excreta, with or without litter, from poultry, ruminants or any other animal except humans, which may or may not include other feed ingredients, and which contains in excess of 15.0% feed ingredients, and which contains in excess of 15.0% moisture. It shall contain no more than 30% combined wood, woodshavings, litter, dirt, sand, rocks, and similar extraneous materials. The specific name of each component material in the product must be declared on the label. (Adopted 1982.)

IFN 2-07-258 Animal-poultry manure and litter processed wet

74.7 Processed Animal Waste Derivative—means a product resulting from the chemical, physical or microbiological alteration of an animal waste. Examples of processed animal waste derivatives are composts, yeasts, algae or other organisms produced from non-human animal wastes, or wastes treated with ammonia, formaldehyde, or other chemicals. The specific name of each such animal waste derivative product must be descriptive, and efficacy and safety data must be submitted and approved before the product is registered or offered for sale. (Adopted 1982.)

IFN 1-07-307 Animal waste processed derivative

## 75. RICE PRODUCTS

Investigator and Section Editor—Jamey Johnson, AR  
Official

75.1 Rice Polishings is a by-product of rice obtained in the milling operation of husking the grain to polish the kernel. (Adopted 1938.)

IFN 4-03-943 Rice polishings

75.2 Ground Rough Rice or Ground Paddy is the entire product obtained in grinding the whole rice grain including the hulls. (Adopted prior to 1928, Amended 1959.)

IFN 4-03-938 Rice grain ground

75.3 Rice Bran, Solvent Extracted is obtained by removing part of the oil from rice bran by the use of solvents and must contain not less than 14% crude protein and not more than 14% crude fiber. (Adopted 1951, Amended 1959.)



light and broken grains and agricultural seeds, weed seeds, hulls, chaff, joints, straw, elevator or mill dust, sand, and dirt. It must be designated as Grain Screenings, Mixed Screenings and Chaff and/or Dust.

No grade of screenings may contain any seeds or other material in amount that is either injurious to animals or will impart an objectionable odor or flavor to their milk or flesh. The screenings must contain not more than four whole prohibited noxious weed seeds per pound and must contain not more than 100 whole restricted noxious weed seeds per pound. The prohibited and restricted noxious weed seeds must be those named as such by the seed control law of the state in which the screenings is sold or used.

EPA allows a "Non-Food/Non-Feed" status for some crops on a state-by-state basis. This allows the producer a wider range of pesticides to use in the production of a seed crop. This is especially important for minor seed crops. In some states alfalfa, clover, carrot and cabbage seed may be designated non-food/non-feed in their state pesticide laws. When so designated there are special labeling, record keeping, and by-product disposal requirements. Most cereal grains and large seeds like bean, pea, and corn have never been allowed a non-food/non-feed status due to their propensity to enter food channels. If you are using seed screenings in the manufacture of a feed, you should check with your state pesticide regulatory authority as to the non-food/non-feed status of that commodity.

All grades of screenings must bear minimum guarantees of crude protein and crude fat and maximum guarantees of crude fiber and ash. (Adopted 1953, Amended 1959, 1960.)

81.1 Grain Screenings is that containing 70% or more grains, including light and broken grains. It may contain wild buckwheat and wild oats. The term "Grain Screenings" may be used for unspecified kinds of grain, or the predominating kind of grain (if in excess of 50%) may be declared as the first word or words in the name. It may contain no more than 6.5% ash. (Proposed 1989, Adopted 1992)

IFN 4-00-542 Barley screenings

IFN 4-20-687 Maize screenings

IFN 4-03-329 Oats screenings

IFN 4-08-085 Rice screenings

IFN 4-27-721 Sorghum screenings

IFN 4-05-216 Wheat screenings

81.2 Mixed Screenings is screenings excluded from the preceding definition. It must contain not more than 27% crude fiber and not more than 15% ash. (Adopted 1953, Amended 1954, 1960.)

IFN 4-02-157 Cereals mixed grain screenings

81.3 Chaff and/or Dust is material that is separated from grains or seeds in the usual commercial cleaning processes. It may include hulls, joints, straw, mill or elevator dust, sweepings, sand, dirt, grains, seeds. It must be labeled, "chaff and/or dust". If it contains more than 15% ash the words "sand" and "dirt" must appear on the label. (Adopted 1953.)

IFN 4-02-149 Cereals--legumes chaff and/or dust

#### 84. SOYBEAN PRODUCTS

Investigator and Section Editor--Tom Waller, IL

##### Official

84.1 Ground Soybeans is obtained by grinding whole soybeans without cooking or removing any of the oil. (Adopted 1933.)

IFN 5-04-596 Soybean seeds ground

84.2 Ground Soybean Hay is the ground soybean plant including the leaves and beans. It must be reasonably free of other crop plants and weeds and must contain not more than 33% crude fiber. (Adopted 1944, Amended 1964.)

IFN 1-04-559 Soybean hay sun-cured ground

84.3 Soybean Hulls consist primarily of the outer covering of the soybean. (Adopted 1948.)

IFN 1-04-560 Soybean seed coats (hulls)

\*84.4 Soybean Feed, Solvent Extracted, is the product remaining after the partial removal of protein and nitrogen free extract from dehulled solvent extracted soybean flakes. The words "Solvent Extracted" are not required when listing as an ingredient in a manufactured feed. (Adopted 1948, Amended 1960, 1964.)

IFN 5-04-613 Soybean seeds low protein low carbohydrates meal solvent extracted

84.8 Soybean Mill Feed is composed of soybean hulls and the offal from the tail of the mill which results from the manufacture of soy grits or flour. It must contain not less than 13% crude protein and not more than 32% crude fiber. (Proposed 1960, Adopted 1961, Amended 1964.)

IFN 4-04-594 Soybean flour by-product

84.9 Soybean Mill Run is composed of soybean hulls and such bean meats that adhere to the hulls which results from normal milling operations in the production of dehulled soybean meal. It must contain not less than 11% crude protein and not more than 35% crude fiber. (Proposed 1960, Adopted 1961, Amended 1964.)

IFN 4-04-595 Soybean mill run

84.10 Soy Phosphate or Soy Lecithin is the mixed phosphatide product obtained from soybean oil by a degumming process. It contains lecithin, cephalin, and inositol phosphatides, together with glycerides of soybean oil and traces of tocopherols, glucosides, and pigments. It must be designated and sold according to conventional descriptive grades with respect to consistency and bleaching. (Proposed 1958, Adopted 1961.)

IFN 4-04-562 Soybean lecithin

84.11 Heat Processed Soybeans is the product resulting from heating whole soybeans without removing any of the component parts. It may be ground, pelleted, flaked, or powdered. The maximum pH rise using standard urease testing procedure should not exceed 0.10 pH units. It must be sold according to its crude protein, crude fat and crude fiber content. (Proposed 1960, Adopted 1964, Amended 1991, Adopted 1992)

IFN 5-04-597 Soybean seeds heat processed

84.12 Soy Protein Concentrate is prepared from high quality sound, clean, dehulled soybean seeds by removing most of the oil and water soluble non-protein constituents and must contain not less than 65% protein on a moisture-free basis. (Proposed 1988, Adopted 1990)

IFN 5-32-183 Soybean protein concentrate

84.13 Kibbled Soybean Meal is the product obtained by cooking ground solvent extracted soybean meal, under pressure and extruding from an expeller or other mechanical pressure device. It must be designated and sold according to its protein content and shall contain not more than 7% crude fiber. (Proposed 1969, Adopted 1971.)

IFN 5-09-343 Soybean seeds kibbled solvent extracted



84.14 Soybean Solubles, Condensed, is the product resulting from the washing of soy flour or soybean flakes with water and acid; water, alkali and acid; or water and alcohol. The wash water is then concentrated to a solids content of not less than 50%. (Proposed 1983, Adopted 1990)

IFN 5-09-344 Soybean solubles condensed

84.15 Ground Extruded Whole Soybeans is the meal product resulting from extrusion by friction heat and/or steam, whole soybeans without removing any of the component parts. It must be sold according to its crude protein, fat, and fiber content. (Proposed 1974, Adopted 1975.)

IFN 5-14-003 Soybean seeds extruded ground

84.16 Protein Modified is a Soybean Product that has been processed to primarily modify the natural protein structure by utilizing acids, alkalies or other chemicals and without removing significant amounts of any nutrient constituent. The defined name under Section 84 of the applicable soybean product so modified shall be declared in the product name. (Proposed 1982, Adopted 1983.)

IFN 5-26-010 Soybean protein product chemically modified

84.17 Soybean Solubles, Dried, is the product resulting from the washing of soy flour or soybean flakes with water and acid; water, alkali and acid; or water and alcohol. The wash water is then dried. (Proposed 1983, Adopted 1990)

IFN 5-16-733 Soybean Solubles dehydrated

84.5 Soy Grits is the granular material resulting from the screened and graded product after removal of most of the oil from selected, sound, clean and dehulled soybeans by a mechanical or solvent extraction process. It must contain not more than 4.0% crude fiber. (Proposed 1978, Adopted 1980.)

IFN 5-12-176 Soybean grits mechanical extracted

IFN 5-04-592 Soybean grits solvent extracted

84.7 Soybean Meal, Dehulled, Solvent Extracted is obtained by grinding the flakes remaining after removal of most of the oil from dehulled soybeans by a solvent extraction process. It must contain not more than 3.5% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (Special Purpose Products) to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. When listed as an ingredient in a manufactured feed it may be identified as "Dehulled Soybean Meal." The words "Solvent Extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1989, Adopted 1992)

IFN 5-04-612 Soybean seeds without hulls meal solvent extracted.

84.51 Soy Flour is the finely powdered material resulting from the screened and graded product after removal of most of the oil from selected, sound, cleaned and dehulled soybeans by a mechanical or solvent extraction process. It must contain not more than 4.0% crude fiber. (Proposed 1978, Adopted 1980.)

IFN 5-12-177 Soybean flour mechanical extracted

IFN 5-04-593 Soybean flour solvent extracted

84.60 Soybean Meal, Mechanical Extracted is the product obtained by grinding the cake or chips which remain after removal of most of the oil from soybeans by a mechanical extraction process. It must contain not more than 7.0% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (Special Purpose Products) to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. The words "Mechanical Extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1989, Adopted 1992)

IFN 5-04-600 Soybean seeds meal mechanical extracted.

84.61 Soybean Meal, Solvent Extracted is the product obtained by grinding the flakes which remain after removal of most of the oil from soybeans by solvent extraction process. It must contain not more than 7.0% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (Special Purpose Products) to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. The words "Solvent Extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1989, Adopted 1992)

IFN 5-04-604 Soybean seeds meal solvent extracted.

84.62 Soy Protein Isolate is the major proteinaceous fraction of soybeans prepared from dehulled soybeans by removing the majority of non-protein components and must contain not less than 90% protein on a moisture-free basis. (Proposed 1988, Adopted 1990)

IFN 5-24-811 Soy Protein Isolate

84.63 Hydrolyzed Soy Protein is made from soybean flours, concentrates or isolates, treated with an acid or a base or an enzyme and then dried. (Proposed 1993, Adopted 1994)

84.64 Textured Soy Protein Product is made from defatted soy flour mixed with water and/or steam, extruded and then dried. (Proposed 1993, Adopted 1994)

## 87. SPECIAL PURPOSE PRODUCTS

Investigator and Section Editor—Shannon Jordre, SD

(Anti-caking agents, color additives, condiments, grinding agents, pelleting agents, pigmentation, stabilizing agents, etc.)

It is impracticable to list all special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, in the Official Publication.

The Association of American Feed Control Officials regard such common special purpose feed ingredients as salt, sugar, and pepper as safe for their intended use, when used in accordance with good manufacturing practice.

The less common special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, are listed in the Official Publication.

The least common special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, are listed in the Code of Federal Regulations; Title 21, Food and Drugs; Chapter 1—Food and Drug Administration, Department of Health and Human Services; Sub-Chapter A—General; Part 73—Color Additives, or Part 74—Color Certification, or Sub-Chapter E—Animal Drugs, Feeds, and Related Products; Part 573—Food Additives Permitted in Feed and Drinking Water of Animals or Part 582—Substances Generally Recognized as Safe or Part 584—Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals.

A number of ingredients have been approved by the FDA Informal Review Process (I.R.P.) (see AAFCO Official Publication 1982—page 223).

### Official

87.1 Algae Meal, a color additive is a dried mixture of algae cells (genus *Sporococcum* separated from its culture broth), molasses, corn steep liquor, and a maximum of 0.3% ethoxyquin. (Reg. 73.275, Subpart D, Color Additives.) (Proposed 1962, Amended 1963, Adopted 1964, Amended 1975.)

IFN 5-00-357 Algae whole meal

87.2 Lignin Sulfonate is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (*Musa textilis*) or of Sisal (*Agave sisalana*) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed 6 percent by weight). It may be used in animal feed in amounts calculated on a dry weight basis, as: (1) A pelleting aid, in the liquid or dry form, in an amount not to exceed 4 percent of the finished pellets. (2) A binding aid, in the liquid form, in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain. (3) A surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses. (4) A source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4 percent of the finished feed. Reg. 573.600. (Proposed 1963, Adopted 1964, Amended 1970, 1971 and 1973.)

IFN 8-02-627 Lignin sulfonate dehydrated

IFN 8-29-786 Lignin sulfonate condensed

87.3 Silicon Dioxide is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. It is used in the following feeds or feed components as an anti-caking agent, and/or grinding aid as follows: (Reg. 573.940) (Proposed 1964, Adopted 1965.)

IFN 8-08-034 Silicon dioxide SiO<sub>2</sub>

Feed or Feed Component	Limitation Percent
BHT (Butylated Hydroxy Toluene)	2
Finished Feed	2
Methionine Hydroxy Analogue and its Calcium Salts	1
Sodium Propionate	1
Urea	1
Vitamins	3

87.4 Verxite (exfoliated hydrobiotite), an additive, is a magnesium-aluminum-iron silicate conforming to one of the following:

Verxite Granules contain a minimum of 98% Hydrobiotite, is thermally expanded and has a bulk density of 5 to 9 pounds per cubic foot.

IFN 8-08-993 Verxite granules

It is used or intended for use in poultry feed at a level not to exceed 5% of the weight of the finished feed as a non-nutritive bulking agent for restricting calorie intake in pullet replacement feeds, or as anticaking or blending agent, pelleting aid, or non-nutritive carrier for the incorporation of nutrients in poultry, swine, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5% of the dog feed or 5% of the final feed for other animals.

Verxite Flakes contain a minimum of 98% Hydrobiotite and has a bulk density of 20 to 30 pounds per cubic foot.

IFN 8-08-994 Verxite flakes

It is used or intended for use as an anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1% by weight of the final feed for ruminants.

Verxite Grits contains a minimum of 80% Hydrobiotite. It has a bulk density of from 40 to 50 pounds per cubic foot.

IFN 8-09-350 Verxite grits

It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and is in no case to exceed one percent by weight of the final feed.

To assure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the act the name of the additive (verxite granules or verxite flakes or verxite grits) and when the additive is present in excess of 1%, a statement of the quantity of the additive contained therein and the term "non-nutritive" in juxtaposition therewith. (Reg. 573.1000) (Proposed 1961, Adopted 1964, Amended 1968 and 1969.)

#### Tentative

T87.23 Cassia Gum is the purified flour from the endosperm of the seeds of *Cassia tora* or *Cassia obtusifolia*, which belong to the family Leguminosae. It is a galactomannane comprised of at least 75% polysaccharide consisting primarily of a linear chain of 1,4-B-D-mannopyranose units. The ratio of galactose to mannose is 1:5. Cassia gum is the product obtained by mechanical separation of the endosperm from the germ and husk in a heated process, with subsequent purification by sieving, pulverization, extraction, and drying. It contains not more than 10 ppm chrysophanic acid. Cassia gum is suitable for use as a stabilizer (thickening and gelling agent) in canned dog and cat food and shall be permitted at concentrations up to 4000 ppm. (Proposed 1999)



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## 87.5 Additional Special Purpose Products:

Name	FDA Regulation	Classification Under Food Additives Amendment	Limitations or Restrictions			
Aluminum Sulfate IFN 8-20-861	Reg. 582.1125	Anti-gelling agent for molasses, dewater of beet pulp	••None	Reg. 582.10	Spices, seasonings, essential oils, etc.	Not to exceed 0.06% of the diet
Anise Seed IFN 8-00-416	Reg. 582.10	Spices, seasonings, essential oils, oleo resins, and natural extracts	••None	Reg. 582.20	Spices, seasonings, essential oils, etc.	••None
Astaxanthin	21 CFR 73.35	Tissue pigment	Salmonid feed only	Reg. 582.1	Anti-caking agent (in non-medicated feeds)	Not to exceed 5% in vitamin preparations
Attapulgite Clay IFN 8-14-008	Reg. 582.1 (in non-medicated feeds)	Anti-caking agent and pelleting aid	••Not to exceed 2% in finished feed	Reg. 582.1	Anti-caking agent (in non-medicated feeds)	Not to exceed 0.0025% (25 ppm) in the finished feed
		Suspension aid in liquid feed supplement	••Not to exceed 2.5% in supplement	Reg. 582.1400	Stabilizer	••Not to exceed 2.5% in finished feed
Ball Clay			Not accepted for use as a feed ingredient	Reg. 582.7343	Stabilizer	••None
Calcium Silicate IFN 8-08-043	Reg. 573.260	Anti-caking agent	Not to exceed 2%			None
Calcium Aluminates		Pellet binder	Maximum of 2% in poultry, swine and rodent feeds, and a maximum 1% in feed for all other species.	Reg. 573.660	Die lubricating and release agent in the tabletting process	GMP
Calcium Stearate IFN 8-09-345	Reg. 573.280 (Feed Grade)	Anti-caking agent	In accordance with good manufacturing practice	Reg. 573.680	To reduce dustiness of feed or mineral supplements, to serve as a lubricant in the preparation of pellets, cubes, and blocks, to improve resistance to moisture of such pellets, cubes, and blocks, and to prevent segregation of trace minerals in mineralized salt	Not to exceed 0.032% (320 ppm) in the molasses
Canthaxanthin	21 CFR 73.75	Broiler chicken skin pigment	Not to exceed 4 grams/ton of the complete feed			Not to exceed 3% in mineral supplements. Not to exceed 0.06% of the total ration.
Carrageenan	21 CFR 172.620	Emulsifier, stabilizer or thickener for pet foods.	To be refined only from those red seaweed sources listed in 21CFR 172.620			To serve as a diluent carrier in the manufacture of feed grade biuret.
Capsicum; Red Pepper IFN 8-03-485	Reg. 582.10	Spices, seasonings, etc.	••None	Reg. 582.4505	Emulsifying Agent	None
Chondrus extract IFN 8-07-247	Reg. 582.7255	Stabilizer	None			None
Dicalcyl tartrate acid esters of mono and diglycerides of edible fats or oils, or edible fat-forming fatty acids.	Reg. 582.4101	Emulsifying Agent	None	Reg. 582.1	Spices, seasoning, etc.	••None
Diatomaceous Earth IFN 8-09-363	Reg. 573.340	Inert Carrier and Anti-caking agent	Not to exceed 2% of total ration	Reg. 582.4521	Emulsifying Agent	None
Disodium EDTA IFN 8-05-489	Reg. 573.360	To solubilize trace minerals in aqueous solutions.	Not to exceed 0.024% (240 ppm) in finished feed			
Ethyl Cellulose IFN 4-08-045	Reg. 573.420	Binder or filler in dry vitamin preparations	••None	Reg. 582.1 (in non-medicated feeds)	Anti-caking aid, pelleting aid, and non-nutritive carrier	Not to exceed 2% of the finished material
Ethoxylated mono and diglycerides	Reg. 172.834	Emulsifier	Not to exceed 0.5% in dry milk replacers		Dust control agent	Not to exceed 3% in mineral supplements. Not to ex-
Fenel IFN 8-01-855	Reg. 582.10	Spices, seasonings, essential oils, etc.	••None			
Fenugreek Seed IFN 8-01-856	Reg. 582.10	Spices, seasonings, essential oils, etc.	••None			

Petrolatum or a combination of mineral oil and petrolatum IFN 8-05-691	Reg. 573.720	To reduce dustiness of feed or mineral supplements, to serve as a lubricant in the preparation of pellets, cubes, and blocks, to im- prove resistance to moisture of such pellets, cubes, and blocks	Not to exceed 0.06% of the total ration	Not to exceed 3% in mineral supple- ments. Not to ex- ceed 0.06% of the total ration	Letters of 8/5/83 and 4/6/86	Finishing Agent & Anticaking Agent	Not to exceed 10% as a carrier in animal feed premises **None
Petroleum Jelly IFN 8-08-029	Reg. 573.720	Dust control agent in mineral mixes	Not to exceed 3% in mineral supple- ments. Not to ex- ceed 0.06% of the total ration	**None	Reg. 582.6789	Dispersant	Not to exceed 1% of the finished product.
Phosphoric Acid IFN 6-03-707	Reg. 582.1073	Misc. and/or general purpose	Not to exceed 0.025% (250 ppm) in the molasses	**None	Reg. 582.1	Coating for feed grade urea for rumi- nant animal feed	Not to exceed 1% of the finished ma- terial
Polyethylene Glycol (400) mono and diolate	Reg. 573.800	Processing aid when present as a result of its additions to molasses	Not to exceed 0.025% (250 ppm) in the molasses	**None	Reg. 573.1010	Stabilizer, emulsi- fier, thickener, suspending agent or bodying agent in: Calf Milk Re- placers and Liquid Feed Supplements	0.1% in Calf Milk Replacers (as fed), and 0.25% in Liquid Feed Supplements
Polyoxyethylene Glycol (400) mono & diolates IFN 8-09-348	Reg. 573.820	Emulsifier	Calf Milk Replacers		Reg. 573.1020	Anti-caking agent in salt	Not to exceed 0.0013% (13 ppm)
Polyisobutylene IFN 8-08-053	Reg. 573.860	Emulsifier	Calf Milk Replacers		Reg. 172.510	Flavoring Agent	Minimum quantity necessary to produce intended effect
Polypropylene Glycol IFN 8-03-809	Reg. 573.860	Emulsifier	Calf Milk Replacers and mineral pre- mixes				
Pyrophosphate IFN 8-05-694	Reg. 582.1666	Emulsifying agent	GRAS except in Cat Food				
Saccharin Sodium IFN 8-04-103	Reg. 573.900	Anti-caking aid, blending agent, pel- leting aid, or carrier sweeteners	Not to exceed 2% of the complete feed				
Sodium Bisulfate	*GRAS	Non-nutritive General Purpose feed additive	**None				
Sodium carboxymethyl- cellulose IFN 8-08-100	Reg. 582.1745	Stabilizer	within a range of 2-10 pounds per ton. Not to exceed 2% in finished feed				
Sodium aluminate IFN 8-08-101	Reg. 582.2777	Anti-caking agent	Not to exceed 2% in finished feed				
Sorbitan mono- stearate with or without Polyisobutylene IFN 8-05-695	Reg. 573.960	Emulsifier in min- eral premixes and dietary supplement for animal feed	**None				
Taigetics (Asteo Marigold) Meal & extract IFN 8-05-696	Reg. 73.295 (Color Additive)	To enhance the yel- low color of chicken skin & eggs	Sufficiently supple- mented with rantho- phyll and associated carotenoids so as to accomplish the in- tended effect				
Talc	FDA/CVM/DAF	Die Lubricant,	Not to exceed 2% in the				

\*\*\*NOTE: Attapulgite Clay, Bentonite, and Kaolin are "GRAS" in non-medicated feeds as binders or pelleting aids when used in accordance with good manufacturing practices and do not exceed the limitations listed above. These special purpose products are not prohibited in medicated feeds for the same purpose and at the same level when it can be demonstrated that they do not interfere with the analysis of the drug by acceptable methods. It is the manufacturer's responsibility to determine and submit adequate data to support the conclusion that interference does not occur before using these products in a feed containing a drug. Based on current information, these products are acceptable for use in medicated feeds containing the following drugs:

Aklomide plus Sulfanitran	Nitrofurazone
IFN 8-12-184	IFN 8-03-234
Chlortetracycline	Nitromide
IFN 8-01-224	IFN 8-05-560
	4 Nitrophenyl-Arsonic Acid
	IFN 8-05-561
	Roxarsone
	IFN 8-12-190
Lasalocid Sodium	Sulfanilamide
IFN 6-26-333	IFN 8-12-191
Lincomycin Hydrochloride	Sulfathiazole
IFN 8-12-192	IFN 8-04-704
Melengestrol Acetate	Sulfaquinoxaline
IFN 8-08-817	IFN 8-04-703

\*GRAS—Abbreviation for the phrase "Generally Recognized as Safe." A substance which is generally recognized as safe by experts qualified to evaluate the safety of the substance (for its intended use.)

\*\*None—No quantitative restrictions although use must conform to good manufacturing practices.

**Monensin**  
IFN 8-09-373

Based on current information found in the new animal drug regulations (part 558) the following drugs are not permitted in animal feeds containing bentonite because bentonite has been shown to interfere with the analysis of the drugs by the acceptable methods:

Amprolium	558.55
IFN 8-00-373	
Buquinolate	558.105
IFN 8-08-103	
Carbadox	558.115
IFN 8-20-775	
Decoquinat	558.195
IFN 8-09-371	
Morantel tartrate	558.360
IFN 8-16-451	
Nequinat	558.365
IFN 8-09-828	
Oleandomycin	558.435
IFN 8-03-412	
Pyrantel Tartrate	558.485
IFN 8-14-011	
Robenidine	
hydrochloride	558.515
IFN 8-14-012	
Thiabendazole	558.615
IFN 8-04-827	

**Tylosin**  
IFN 8-05-069

NOTE: International feed name and AAFCO names are identical for these 24 drugs.

**87.6 Rice By-Products Fractions** is obtained by screening and aspirating Ground Rice Hulls. It is used primarily as a pelleting aid and is composed of such fine particles of Ground Rice Hulls, Spongy Parenchyma, and minute amounts of Rice Flour, Rice Germ, Pericarp, and Rice Starch as will pass an 80 mesh screen and contain not less than 5% crude protein, 1.5% crude fat, and not more than 25% crude fiber. (Proposed 1965, Adopted 1966, Amended 1967.)

**IFN 1-08-033 Rice hull fines**

**87.7 Ammoniated Rice Hulls** is obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 F and a pressure of 175 lb. per square inch. It is to be used in beef cattle feeds at a level not to exceed 20% of the total rations as a source of crude fiber and as the sole source of non-protein nitrogen. The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information.

- (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.
- (3) Directions for use to provide not more than 20% of the additive in the total ration and a prominent statement: "Warning--This feed should be used only in accordance with the directions furnished on the label." (Reg. 573.160.) (Proposed 1966, Adopted 1968.)

**IFN 1-05-698 Rice hulls ammoniated**

**87.8 Polyethylene Roughage Replacement** consists of basic polymers manufactured by the catalytic polymerization of ethylene, is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters:  $0.9 \pm 0.1 \times 0.8 \pm 0.1 \times 1.2 \pm 0.1$ . It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle. The labels and labeling shall bear the name of the additive "Polyethylene Roughage Replacement," and adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per day for 6 successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution. (Proposed 1969, Adopted 1970.) Reg. 573.780

**IFN 8-09-351 Polyethylene**

**87.9 Ammoniated Cottonseed Meal** is obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached. It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 20% of the total ration.

The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

- (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from non-protein nitrogen.
- (3) Directions for use to provide not more than 20% of the additive in the total ration and a prominent statement: "Warning--This feed should be used only in accordance with the directions furnished on the label." (Reg. 573.140) (Proposed 1969, Adopted 1970.)

**IFN 5-09-352 Cotton seeds meal solvent extracted ammoniated**

**87.10 Poloxalene** consists of polyoxypropylene-polyoxyethylene glycol non-ionic block polymer. It may be used as a surfactant for the flaking of feed grain, when added to liquid grain conditioner in an amount not to exceed 1% of the conditioner, and the conditioner is added to the feed grain at a rate of 1 quart per ton of feed grain. (Reg. 573.760) (Proposed 1970, Adopted 1971.)

**IFN 8-08-063 Poloxalene**

**87.11 Anhydrous Ammonia** is applied to corn plant material prior to ensiling as a source of nonprotein nitrogen in accordance with any one of the following methods:

- (1) As a component of an aqueous premix containing 16 to 17 percent ammonia, with molasses, minerals, and not less than 83 percent crude protein. The labeling must bear the following statements:
  - a) An expiration date of not less than 10 weeks after date of manufacture,
  - b) additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day or beef cattle consuming less than one percent of their body weight daily in shelled corn, and
  - c) do not use additional trace mineral supplementation with treated silage;
- (2) After being diluted to a 15 to 30 percent aqueous ammonia solution (by weight) and:
  - a) does not exceed anhydrous ammonia equivalent to 0.3 percent of the corn plant material,
  - b) the corn plant material contains 28-38 percent dry matter, and
  - c) the treated silage is fed to dairy cattle only; and
- (3) Directly, and

- a) does not exceed anhydrous ammonia equivalent to 0.35 percent of the corn plant material.
- b) the corn plant material contains 30 to 35 percent dry matter.
- c) 75 to 85 percent of the anhydrous ammonia is liquid at ambient pressure during the direct application, and
- d) the treated material is used in dairy or beef cattle rations.

The labeling of the article must contain the following information in addition to any other required information:

- (1) The name of the article.
- (2) The concentration of ammonia.
- (3) The maximum percentage of equivalent crude protein from nonprotein nitrogen
- (4) Directions for use consistent with 1) (b) and (c), 2) (c), and 3) (d) above, and
- (5) A prominent "Warning-- This feed should be used only in accordance with the directions furnished on the label. (Proposed 1974, Adopted 1975, Revised 1982, Adopted 1983.) Reg. 573.180

#### IFN 5-14-511 Ammonia anhydrous

87.12 Bentonite is a naturally occurring mineral consisting primarily of the tri-layered aluminum silicate, montmorillonite. It may contain calcium or sodium as the predominant available or exchange ion. It is used or intended for use in non-medicated animal feed as an anti-caking agent and pelleting aid in an amount not to exceed 2% in total ration. It is not prohibited in medicated animal feed for the same purposes and at the same levels when it can be demonstrated that it does not interfere with the bioavailability of the medicament to animals and the analysis of the feed for the medicament by acceptable methods. It is the manufacturer's responsibility to determine and submit adequate data to support the conclusion that interference does not occur before using it in a feed containing medicaments. Medicaments with which it may currently be used are listed in 87.5. (Proposed 1974, Adopted 1975.) Reg. 582.1155

#### IFN 8-00-695 Bentonite

87.13 Sodium Bentonite is a naturally occurring mineral consisting primarily of the tri-layered hydrous aluminum silicate, montmorillonite characterized by a sodium exchange or available ion content of not less than 1% and not more than 2% of the air dried material. It is used or intended for use in non-medicated animal feed as an anti-caking agent and pelleting aid in an amount not to exceed 2% in total ration. To reduce seepage in silage, the amount added would not exceed 1% sodium bentonite. It is not prohibited in medicated animal feed for the same purposes and the same levels when it can be demonstrated that it does not interfere with the bioavailability of the medicament to animals and the analysis of the feed for the medicament by acceptable methods. It is the manufacturer's responsibility to determine and submit adequate data to support the conclusion that interference does not occur before using it in a feed containing medicaments. Medicaments with which it may currently be used are listed in 87.5. (Proposed 1974, Adopted 1975, Amended 1983.) Reg. 582.1155

#### IFN 8-14-512 Sodium bentonite

87.14 Powdered Cellulose is purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant materials. (Proposed 1975, Adopted 1976.)

#### IFN 1-15-514 Cellulose powdered

87.16 Chitosan is a cationic carbohydrate polymer intended for use as a precipitating agent of proteinaceous material from food processing plants. It is chemically derived by deacetylation of the naturally occurring chitin in crab and

shrimp shells. It may be used in an amount not to exceed that necessary to accomplish its intended effect. Chitosan when fed as a component of feed to livestock shall be present at no more than 0.1% of the feed. Proteinaceous material coagulated with chitosan must have safety and efficacy data approved before it can be registered or offered for sale. (Proposed 1984, Adopted 1985.) IFN 8-17-730 Chitosan

87.19 Urea Formaldehyde Condensation Polymer is a pelleting aid for use in animal feeds, excluding aquatic species. Restrictions: Not to exceed 0.1 ppm free formaldehyde in the finished pelleted product. (Proposed 1989, Adopted 1990)

#### IFN 8-30-422 Urea Formaldehyde Condensation Polymer

87.17 Perlite is the expanded, powdered form of a glassy volcanic rock, consisting essentially of fused sodium potassium aluminum silicate. It meets the specifications of current edition and supplements of the Food Chemicals Codex. It is used as a filler aid or pressing aid in the processing of foods and feed ingredients and also may be used as an anti-caking agent. It may not exceed 4% by weight of the product in which it is present as a processing aid. (Proposed 1977, Amended 1978, Adopted 1979.) IFN 8-26-242 Perlite

#### Tentative

T87.15 Formaldehyde Solution is produced by dissolving about 37% by weight of formaldehyde gas in water usually with 10 to 15% methanol added to prevent polymerization. (1) It is used to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing a dry, free-flowing product; an aqueous blend of soybean and sunflower meals in a ratio of 3:1 is mixed with animal fat in a ratio of 3:2 and formaldehyde (37% solution) is added at a level of 4% of the dry matter weight of the mixture which, upon drying contains not more than 1% formaldehyde and 12% moisture. The mixture is used as a component of dry, nonpelleted feeds for beef and nonlactating dairy cattle. To assure safe use of the additive the label of the mixture shall bear the name of the additive and adequate directions for use providing that feed as consumed is not to contain more than 25% of the mixture and (2) it is used at the rate of 5.4 pounds (2.5 kilograms) per ton of poultry feed. At this level, it is an antimicrobial agent used to maintain complete poultry feeds salmonella negative for up to 14 days. To assure safe use of the additive, in addition to other information required by 21CFR 573.460, the label and labeling shall contain: [a] the name of the additive, [b] a statement that formaldehyde solution which has been stored below 40 F or allowed to freeze should not be applied to complete poultry feeds, and [c] adequate direction for use including a statement that formaldehyde should be thoroughly mixed into complete poultry feeds and that the finished poultry feed shall be labeled as contains formaldehyde. (Proposed 1977, Adopted 1978, Amended 1996.)

#### IFN 8-26-243 Formaldehyde solution

T87.18 Reed-Sedge Peat is a natural, partially decomposed plant material, formed from a mixture of reeds, sedges, grasses and some hypanum mosses occurring in wetlands and containing one third to two thirds peat fibers. It should be dehydrated to a moisture content of not more than 15% and be in a state free from all harmful micro-organisms. It is intended for use in animal feed as a carrier for liquid products and premixes or as a nutritional diluent for lowered energy diets at a level not to exceed 5% of the total daily ration. (Proposed 1986)

#### IFN 1-18-898 Peat Whole Dehydrated

T87.21 Kraft Lignin and its salts (ammonium, calcium, magnesium or sodium) is obtained from the acid precipitation of lignin from spent black liquor produced in the sulfate digestion process of wood and is dehydrated to less than 8 percent moisture by weight. It is used; (1) as an aid in recovering proteinaceous material during the rendering process, limited to 0.1 percent of the crax, (2) in the clarification of spent grease, and (3) as a coating agent for fat soluble vitamins limited to 50 percent of the vitamin premix matrix and 3 percent of the finished feed. (Proposed 1993, Amended 1994)

T87.22 Microcrystalline Cellulose is purified, partially depolymerized cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant material by treating with mineral acids. (Proposed 1995)

#### 90. VITAMINS

Investigator and Section Editor—Julie Zimmerman, CO  
Official

90.1 Cod Liver Oil is the oil obtained from the livers of gadus morrhuae or other species of the family gadidae, either or both. It must contain not less than 385,900 International Units of vitamin A per pound (850 units per gram) and not less than 29,510 International Chick Units of vitamin D per pound (65 units per gram). (Adopted 1937, Amended 1945, 1950, 1973, 1995, 1996)

IFN 7-01-993 Fish cod liver oil

90.2 Cod Liver Oil with Added Vitamins A and D is the product consisting of cod liver oil to which has been added vitamins A and D. The product must contain not less than 136,000 International Chick Units of vitamin D per pound (300 per gram). (Adopted 1948, Amended 1950, 1964, 1967.)

IFN 7-08-047 Fish cod liver oil vitamins A and D added

90.3 Vitamin A Oil is an oil of animal or vegetable origin with or without vitamin A supplementation for which vitamin A potency is claimed. (Adopted 1944, Amended 1945, 1959, 1964, 1967.)

IFN 7-05-141 Vitamin A oil

90.4 Vitamin D<sub>2</sub> Supplement is a feeding material used for its vitamin D<sub>2</sub> activity. It must contain a minimum of 100,000 International Units of vitamin D<sub>2</sub> per pound. (Adopted 1956, Amended 1973, 1995, 1996)

IFN 7-05-149 Vitamin D<sub>2</sub> supplement

90.5 Vitamin D Oil is an oil of animal or vegetable origin with or without vitamin D supplementation for which vitamin D potency is claimed. (Adopted 1944, Amended 1945, 1959, 1964, 1967.)

IFN 7-05-147 Vitamin D oil

90.6 Vitamin A and D Oil is an oil of animal or vegetable origin with or without vitamins A and D supplementation for which vitamin potencies are claimed. (Adopted 1944, Amended 1945, 1950, 1959, 1964, 1967.)

IFN 7-05-145 Vitamin A and D oil

90.7 Cholecalciferol (D-Activated Animal Sterol) is obtained by activation of a sterol fraction of animal origin with ultra-violet light or other means. For label identification it may be followed with the parenthetical phrase (Source of Vitamin D<sub>3</sub>). (Adopted 1942, Amended 1993.)

IFN 7-00-408 Animal sterol irradiated

90.8 Ergocalciferol (D-Activated Plant Sterol) is obtained by activation of a sterol fraction of plant origin with ultra-violet light or other means. For label identification it may be followed with the parenthetical phrase (Source of Vitamin D<sub>2</sub>). (Adopted 1944, Amended 1993.)

IFN 7-03-728 Plant sterol irradiated

90.11 Vitamin B<sub>12</sub> Supplement is a feeding material used for its vitamin B<sub>12</sub> activity. It must contain a minimum vitamin B<sub>12</sub> activity of 1.5 milligrams per pound. The term must not be applied to products for which there are accepted names and definitions. (Adopted 1952.)

IFN 7-05-146 Vitamin B<sub>12</sub> supplement

90.12 Vitamin E Supplement is a feeding material used for its vitamin E activity. It must contain a minimum vitamin E activity equal to 10,000 International Units of vitamin E per pound. (Adopted 1953, Amended 1967.)

IFN 7-05-150 Vitamin E supplement

90.13 Riboflavin Supplement is a feeding material used chiefly for its riboflavin content, and must contain not less than 1,000 milligrams of riboflavin per pound. The label must bear a parenthetical statement of origin immediately following this declaration. (Adopted 1957.)

IFN 7-03-921 Riboflavin supplement

90.14 Vitamin A Supplement is a feeding material used for its vitamin A content. It must contain a minimum of two million International Units of vitamin A per pound. The label must bear a statement of the source of vitamin A and a minimum guarantee of International Units of vitamin A per pound with additional permissive International Units of vitamin A per gram. (Proposed 1959, Adopted 1960, Amended 1973, 1995, 1996)

IFN 7-05-144 Vitamin A supplement

90.15 Vitamin D<sub>3</sub> Supplement is a feeding material used for its vitamin D<sub>3</sub> activity. It must contain a minimum of 100,000 International Chick Units of vitamin D<sub>3</sub> per pound. (Proposed 1966.)

IFN 7-05-699 Vitamin D<sub>3</sub> supplement

90.16 Niacin Supplement is a term that may be used in the ingredient list on a feed label of a mixed feed to indicate the addition of either Niacin or Niacinamide. Sources containing only Niacin or Niacinamide must state the source of Niacin on their label. (Adopted 1980, Amended 1981.)

IFN 7-26-003 Niacin supplement

90.17 Betaine (hydrochloride or anhydrous) is the crystalline chloride of betaine or anhydrous betaine; a partial replacement for choline. (Proposed 1990, Adopted 1991)

IFN 7-00-722 Betaine hydrochloride

NOTE: USP Units and International Units are Synonymous.

90.25 ADDITIONAL OFFICIALLY RECOGNIZED VITAMIN  
INGREDIENTS FOR ANIMAL FEED USE AT NUTRITIONAL LEVELS  
AND IN CONFORMITY WITH CURRENT GOOD MANUFACTURING  
PRACTICES

Recognized English Name	Article or Substance Indicated	Status Under Food Additive Amendments 21 CFR
Ascorbic Acid IFN 7-00-433	Crystalline Ascorbic Acid-- Commercial Feed Grade	Reg. 582.5013(GRAS)
L-Ascorbyl-2- Polyphosphate	Stabilized Ascorbic Acid Feed Grade	Aquatic species, guinea pig, primates (non-human)
L-Ascorbyl-2- Sulfate	Stabilized Ascorbic Acid Feed Grade	Aquatic species (Salmon, Trout, Catfish, Shrimp, and Tilapia)
Biotin IFN 7-00-723	Biotin--Commercial Feed Grade	Reg. 582.5159(GRAS)
Calcium Ascorbate	Commercial Grade	Vitamin C activity in dry feeds (< 13% moisture) only
Calcium L-Ascorbyl- 2-Monophosphate	Stabilized Ascorbic Acid Feed Grade, For use in fish feeds only	
Calcium Pantothenate IFN 7-01-079	Crystalline Calcium Panto- thenate--Commercial Feed Grade	Reg. 582.5212(GRAS)
Carotene IFN 7-01-134	The Refined Crystalline Ca- roteno Fraction of Plants	Reg. 582.5245(GRAS)
Choline Chloride IFN 7-01-228	Choline Chloride--Commer- cial Feed Grade	Reg. 582.5252(GRAS)
Choline Pantothenate IFN 7-01-229	Crystalline Choline Panto- thenate--Commercial Feed Grade	
Choline	Choline Xanthate--Com- mercial Feed Grade	Reg. 573.300
Erythorbic Acid (Iso Ascorbic Acid) IFN 7-09-823	Either the Acid or the So- dium Salt	Reg. 582.3041
Folic Acid IFN 7-02-066	Crystalline Folic Acid-- Commercial Feed Grade	
Herring Oil IFN 7-08-048	The Oil Extracted from Whole of Parts of Herring	
Inositol IFN 7-09-354	Vitamin B Complex Vita- min; Lipotropic, Chemical name-Cyclohexandehexol. Also referred to as l-inositol or meso-inositol.	Reg. 582.5370(GRAS)
Magnesium L-Ascorbyl-2- Phosphate	Stabilized Ascorbic Acid	Fish Feeds Only

Menadione  
Dimethylpyri-  
midinol  
Bisulfite  
IFN 7-08-102

Crystalline Menadione--Di-  
methylpyrimidinol Bisulfite  
--Commercial Feed Grade

Reg. 573.620

Menadione Nicotin-  
amide Bisulfite

Source of Vitamin K Activity  
and supplemental Niacin

Chicken and Turkey  
feeds at 2 g/ton  
21 CFR 573.625  
Poultry  
2 to 4 g/T

Menadione Sodium  
Bisulfite

The Addition Product of

Menadione and Sodium Bi-  
sulfite Containing not less

Than 30% of Menadione

The oil extracted from whole

Menhaden

Crystalline Nicotine Acid--

Commercial Feed Grade

Reg. 582.5530(GRAS)

IFN 7-03-219

Niacinamide;

Nicotinamide

IFN 7-03-215

p-Aminobenzoic

Acid

IFN 7-03-513

Pyridoxine

Hydrochloride

IFN 7-03-822

Riboflavin

IFN 7-03-920

Salmon Oil

IFN 7-08-050

Salmon Liver Oil

IFN 7-02-013

Sardine Oil

IFN 7-02-016

Shark Liver Oil

IFN 7-02-019

Thiamine, Thiamine

Hydrochloride

IFN 7-04-828

Thiamine

Mononitrate

IFN 7-04-829

Tocopherol

IFN 7-00-001

a-Tocopherol

Acetate

IFN 7-18-777

Tuna Oil

IFN 7-02-024

Vitamin A

Acetate

IFN 7-05-142

The oil extracted from can-  
nery refuse of Tuna  
Vitamin A Acetate--Com-  
mercial Feed Grade

Reg. 582.5933(GRAS)

Reg. 582.5875(GRAS)

Reg. 582.5878(GRAS)

Reg. 582.5890(GRAS)

Reg. 582.5892(GRAS)



Vitamin A	Vitamin A Palmitate--Com-	Reg. 582.5936(GRAS)
Palmitate	mercial Feed Grade	
IFN 7-05-143		
Vitamin A	Consists of retinol or	
Propionate	esters of retinol formed	
IFN 7-26-311	from edible fatty acids.	
Wheat Germ Oil	The oil extracted or expressed	
IFN 7-05-207	from Wheat Germ	

\*GRAS--Abbreviation for the phrase "Generally Recognized As Safe" by experts qualified to evaluate the safety of the substance for its intended use.

#### 90.26 Source of Vitamins and Their Levels

Vitamin Compound (1)	Vitamin (2)	Vitamin/Vitamin(3) Compound
L-ascorbyl-2-phosphosphate	Ascorbic Acid	0.800
Menadione Dimethylpyrimidinol	Menadione	0.454
Menadione Sodium Bisulfite	Menadione	0.330
Complex		
Riboflavin-5-Phosphate	Riboflavin	0.730
d-Calcium Pantothenate	d-Pantothenic Acid	0.920
Thiamine Hydrochloride	Thiamine	0.892
Thiamine Mononitrate	Thiamine	0.919
Pyridoxine Hydrochloride	Vitamin B-6	0.823
Choline Chloride	Choline	0.868
Choline Bitartrate	Choline	0.469
Ferric Choline Citrate	Choline	0.330
Sodium Ascorbate	Ascorbic Acid	0.889

(1) Term to be used in ingredient statement when declaring fortification, Uniform State Feed Bill, Section 5.

(2) Term to be used in guaranteed analysis statement when guaranteeing the level of the vitamin "Official Rules and Regulations" under Uniform State Feed Bill, Regulations 4(c).

(3) The ratio is based upon molecular weights and may not be proportional to biological activity. (Adopted 1991)

#### 93. WHEAT PRODUCTS

Investigator and Section Editor--Stephen Kendall, OR

##### Official

93.1 **Wheat Bran** is the coarse outer covering of the wheat kernel as separated from cleaned and scoured wheat in the usual process of commercial milling. (Adopted prior to 1928.)

IFN 4-05-190 Wheat bran

93.2 **Wheat Flour** consists principally of wheat flour together with fine particles of wheat bran, wheat germ, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 1.5% crude fiber. (Adopted 1949.)

IFN 4-05-199 Wheat flour less than 1.5% fiber

93.3 **Wheat Germ Meal** consists chiefly of wheat germ together with some bran and middlings or shorts. It must contain not less than 25% crude protein and 7% crude fat. (Adopted 1949, Amended 1953.)

IFN 5-05-218 Wheat germs ground

93.4 **Wheat Mill Run** consists of coarse wheat bran, fine particles of wheat bran, wheat shorts, wheat germ, wheat flour, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 9.5% crude fiber. (Proposed 1959, Adopted 1960.)

IFN 4-05-206 Wheat mill run less than 9.5% fiber

93.5 **Wheat Middlings** consists of fine particles of wheat bran, wheat shorts, wheat germ, wheat flour, and some of the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 9.5% crude fiber. (Proposed 1959, Adopted 1960.)

IFN 4-05-205 Wheat flour by-product less than 9.5% fiber

93.6 **Wheat Shorts** consists of fine particles of wheat bran, wheat germ, wheat flour, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 7% crude fiber. (Proposed 1959, Adopted 1960.)

IFN 4-05-201 Wheat flour by-product less than 7% fiber

93.7 **Wheat Red Dog** consists of the offal from the "tail of the mill" together with some fine particles of wheat bran, wheat germ, and wheat flour. This product must be obtained in the usual process of commercial milling and must contain not more than 4% crude fiber. (Proposed 1959, Adopted 1960.)

IFN 4-05-203 Wheat flour by-product less than 4% fiber

93.8 **Defatted Wheat Germ Meal** is obtained after the removal of part of the oil or fat from wheat germ meal and must contain not less than 30% crude protein. (Proposed 1960, Adopted 1962, Amended 1964.)

IFN 5-05-217 Wheat germs meal mechanical extracted

NOTE: When "Ground Wheat Screenings" are added to any wheat product such screenings added must be limited to ground wheat screenings not exceeding the run of the mill; and screenings from outside sources must not be added. The declaration of "ground wheat screenings" must be made in the name and in the same size type as the product name itself; i.e., "Wheat Bran with Ground Wheat Screenings", "Wheat Shorts with Ground Wheat Screenings".

#### 96. YEAST

Investigator and Section Editor--Fred Gatlin, KS

## Official

96.1 **Primary Dried Yeast or Dried Yeast** is the dried, non-fermentative yeast of the botanical classification *Saccharomyces* which has been separated from the medium in which propagated. It must consist of yeast cells with no fillers and contain not less than 40% crude protein. (Adopted 1955, Amended 1993, Adopted 1997)

IFN 7-05-533 Yeast primary dehydrated

96.2 **Active Dry Yeast** is yeast which has been dried in such a manner as to preserve a large portion of its fermenting power. It must contain no added cereal or filler and must contain not less than 15 billion live yeast cells per gram. (Adopted 1951.) IFN 7-05-524 Yeast active dehydrated

96.3 **Irradiated Dried Yeast, Irradiated \_\_\_\_\_ Dried Yeast** is the dried, non-fermentative yeast which has been subjected to ultraviolet rays in order to produce anti-rachitic potency. (Proposed 1958, Adopted 1959.)

IFN 7-05-529 Yeast irradiated dehydrated

NOTE: When Irradiated Dried Yeast or Irradiated \_\_\_\_\_ Dried Yeast is used as an ingredient of proprietary feeds for four-footed animals, the name may be followed by a parenthetical phrase (Source of Vitamin D2). (Adopted 1945, Amended 1959.)

96.4 **Brewers Dried Yeast** is the dried, non-fermentative, non-extracted yeast of the botanical classification *Saccharomyces* resulting as a by-product from the brewing of beer and ale. It must contain not less than 35% crude protein. It must be labeled according to its crude protein content. (Adopted 1955, Amended 1975, Adopted 1978.)

IFN 7-05-527 Yeast brewers dehydrated

96.7 **Torula Dried Yeast or Candida Dried Yeast** is the dried, non-fermentation yeast of the botanical classification (*torulopsis*) *Candida utilis* (formerly *Torulopsis utilis*) which has been separated from the medium in which propagated. It must contain not less than 40% crude protein. (Adopted 1955, amended 1993) IFN 7-05-534 Yeast torula dehydrated

96.8 **Yeast Culture\*** is the dried product composed of yeast and the media on which it was grown, dried in such a manner as to preserve the fermenting activity of the yeast. The media must be stated on the label. (Adopted 1957.)

IFN 7-05-520 Yeast culture dehydrated

\*NOTE: No reference to media in main ingredient listing is required when yeast culture forms a component of a proprietary mixed feed.

96.9 **Molasses Yeast Condensed Solubles** is obtained by condensing to a syrup consistency the broth remaining after the removal of baker's yeast cells propagated on molasses. (Proposed 1973, Amended 1974.)

IFN 5-14-009 Sugarcane molasses yeast solubles condensed

96.10 **Brewers Liquid Yeast** is the non-fermentative, non-extracted yeast of the botanical classification *Saccharomyces* resulting as a by-product from the brewing of beer and ale. It must contain not less than 35% crude protein on a dry weight basis. The guaranteed analysis shall include the maximum moisture. (Proposed 1976, Adopted 1978.)

IFN 7-20-878 Yeast brewers liquid

## Tentative

T96.11 **Yeast Extract** is the concentration of the solubles of mechanically ruptured cells of a selected strain of yeast, *Saccharomyces cerevisiae*. It may be dried or concentrated. It must contain not less than 9% crude protein. (Proposed 1998)

# MEDICATED FEED PROGRAM AND PREPARING MEDICATED FEED LABELS Section Editor—Jo Gully, FDA

## Definitions:

1. **Animal Drug**, means articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplements to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man; and articles (other than food) intended to affect the structure or any function of the body of animals other than man; and articles intended for use as a component of any articles specified above; but does not include devices or their components, parts, or accessories.

2. **New Animal Drug**, means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such feed, the composition of which is not generally recognized as safe and effective by experts.

3. **Veterinary Feed Directive Drug**, is a drug intended for use in or on an animal feed which is limited by an approved application filed pursuant to section 512 (b) to use under the professional supervision of a licensed veterinarian.

4. **Veterinary Feed Directive**, is issued by a licensed veterinarian in the course of the veterinarian's professional practice and is in compliance with the conditions and indications for use of the drug set forth in the published notice for the approval of the veterinary feed directive drug pursuant to section 512 (b).

5. **Animal feed**, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

6. A **Medicated Feed** is any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment, or prevention of disease of animals other than man or which contains drug ingredients intended to affect the structure or any function of the body of animals other than man. Antibiotics included in a feed at growth promotion and/or feed efficiency levels are drugs and feeds containing such antibiotics are included in the foregoing definition of "Medicated Feed".

7. A **Medicated Free Choice Feed** is a feed that is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. The palatability of the feed, or the way it is made available to the animal limits the daily consumption of the medicated feed. This method of administering drugs includes, but is not limited to, mineral mixes, liquid feed supplement available from a "lick tank", and medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form).

Under section 512 (b) of the Federal Food, Drug, and Cosmetic Act (the Act), a new animal drug must first be approved by the Food and Drug Administration (FDA) for use in free-choice medicated feed formulas by obtaining an approved new animal drug application (NADA, form 356). Each formula must be supported by data that show the drug is stable in the formula, and that the animals do consume the free-choice feed at an acceptable rate to provide the drug